Dear City Councillors,

Thank you for the opportunity to speak in front of you today. My name is Dr. Michelle Jung, and I am a rheumatologist. You may be wondering why a rheumatologist cares about fluoridation of water.

Patients with rheumatologic conditions are at risk of dental caries. Poor dental health in combination with immune compromise can lead to life-threatening infections. For example, patients with Sjogren syndrome often suffer from progressive and severe tooth decay because they cannot produce enough saliva. I also treat patients with various types of inflammatory arthritis, which can lead to the loss of joint mobility and prevent people from performing simple activities of daily living such as brushing their teeth.

During my training in medical school and residency, I have cared for many elderly patients with dementia. I witnessed how many of them suffered silently because they could not brush their teeth or forgot to brush their teeth or forgot to inform someone that they were in pain from dental caries.

Most importantly, I am here today because I am a mother of two young children, and I am very concerned about their oral health. I am fortunate that I can afford dental care. I cannot imagine the stress of parents with lower-income struggling to take their children to dentists when they are already struggling to make their ends meet. As a mother of young children, I am interested in their development and success. Extensive dental decay in children is painful and can impair eating, sleeping, playing and proper development. These children may require dental surgery and exposure to general anesthetic, which may impact brain development.

My colleagues who are family physicians, pediatricians, emergency medicine physicians, infectious disease specialist, and specialists in other fields of medicine can attest to the increased rate of cavities in children following the loss of water flouridation:

I believe that fluoridation of water benefits everyone in the community. Despite the budgetary challenges faced by the city council, I believe that fluoridation of water is a good investment into the health of Calgarians that you represent.

Sincerely,

Michelle Jung

Dr. Michelle Jung, MD FRCPC
Division of Rheumatology
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CITY OF CALGARY
RECEIVED
IN COUNCIL CHAMBER
OCT 29 2019
ITEM: #6.1 CPS2019-0965
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CITY CLERK'S DEPARTMENT

Noah Cooke
October 29, 2019
Address to City Council

Thank you for the opportunity to speak. Honourable Chair, Councillors, Panel of Experts, and Ladies and Gentlemen:

My name is Noah Cooke. I am pursuing a Masters in medical science at the University of Calgary. First, thank you for voting in favour of an O'Brien Report. As a science graduate student I am personally invested in a future Calgary that values evidence-based policy. Now the question is how that evidence, the benefits and risks, are balanced to best serve the well-being of all Calgarians—not only those only those privileged to speak here today, but those whom are unable to – children, the ill, and the socio-economically disadvantaged who could not afford the time off.

The report is definitive that community water fluoridation is both effective at preventing dental decay and is financially cost-effective at doing so. So, let me address question of whether water fluoridation is safe, the only section of the report that was equivocal. We know that the vast majority of research indicates that fluoride is safe, but that a few very recent studies report an association with small decreases in IQ in children.

I am not personally qualified to properly access the validity of the studies in question. However, I would highlight serious concerns regarding the validity of these studies raised by scientific authorities—in terms of design and conduct. As the Canadian Agency for Drugs and Technologies in Health, the CADTH, a federal government agency stated, quote: The study by Green et al., 2019[13] concluded that "*maternal exposure to higher levels of fluoride during pregnancy was associated with lower IQ scores in children aged 3 to 4 years.*"(p. E1) This conclusion was not supported by the data." End quote. Critically, adjusted estimates with a limited number of covariates showed no significant difference in IQ measures—even at 1.0 mg/L, far above the 0.29 mg/L difference between fluoride exposure and non-exposure—yet, this data was never discussed. Why did the authors fail to discuss this data that contradicted their interpretation? Were they unbiased? And study's credibility is called into question because it did not account for important covariates –socioeconomic status, parental IQ, post-natal fluoride exposure, post-natal diet and nutrition, and others. I appreciate that some of these covariates may be difficult and expensive to account for, but that does not diminish concerns that they compromised the findings of the study. These and numerous other limitations make the studies findings suspect, and I urge you to consider the CADTH review and the Green-Till study side by side.

I can appreciate why you are concerned about fluoride's safety. If I was in your position, I think I would feel rather overwhelmed by these dense studies, and think: "I'm really not sure whom to believe, but I don't want to do any harm." I don't envy your position.

Thankfully, you don't have to make this decision yourselves, or assume responsibility for weighing the evidence. The O'Brien report lays out the benefits and the potential risks, and one can argue over exactly how much risk there is. But in fact there are public health authorities whose job it is to weigh the potential risks against the benefits and issue recommendations. Those authorities are Health Canada; the Medical Officer of Health, Dr. Strong; and the Public Health Dentist of Alberta, Dr. Figueiredo; and they recommended fluoridation to you here today.

Why should we trust them? At some point we all reach the limits of our knowledge. I have a background in science but I don't claim for an instant to understand in full all of the epidemiological considerations of the studies in question. I work in an emerging field of health research, studying the microbiome and mental health, and I reach the limits of my knowledge every day. I am really fortunate to work with two accomplished researchers who are internationally respected. Yet despite their success, they are humble. They are quick to commend the contributions of others where it is due, and are the first to recognize the limits of their knowledge and engage the expertise of others. I admire them deeply, and it's for that combination of accomplishment and humility that I *trust* them. And so I ask you, who will you trust? In whom will *we* entrust the solemn duty to weight the benefits and potential risks?

If the most accomplished scientists embody this humility, I would ask all of us to have the humility to place our trust in the public health authorities who are invested with that responsibility *and burden,* and who are eminently qualified.

Councilors, our City has done so much—you have done so much—to create a Calgary with high standard of life. A place that people, families, and business from around the world *choose*, not only for our innovative and skilled workforce but for our ethos of wellbeing and our commitment to equal opportunity—for which preventing dental decay is so essential. A place where children, the elderly, the less fortunate, and those with mental and physical disabilities can live their best every day, contribute to our dynamic community, be part of the energy. Today we place our trust in you to uphold those values, heed the advice of our public health authorities, and restore community water fluoridation.

SPC on Community and Protective Services
Re: Fluoride

October 29, 2019 at 9:30 am
Council Chambers

My name is Robert Schuett. I am a construction law lawyer in town and I manage a local, medium-sized firm. I am here as a layperson~~, so I am happy to cede my extra time to the many experts that are here today. However, I would like to say a few words.~~

As a father of young children and someone that is generally interested in participating in public policy discussions, I am a passionate advocate for the re-adjustment of fluoridation in Calgary's water. Over the last few years I have had the opportunity to read many articles and studies on this issue, much more than I ever thought I would have cared to read. And, I've been fortunate to have had the opportunity to speak to most of you on this topic.

From a read through the O'Brien institute report, it seems that there are no surprises. Like almost anything in life, too much fluoride can be bad and too little is insufficient to provide the benefits sought. Therefore, it is about striking the right balance. Actually, I don't see it as much different from ~~this committees~~ work with respect to the adjustment of speed limits in residential communities. Obviously, excessive speed is not an option but not driving, at least at this time, is not really an option either. Again, it's about finding the right balance that provides the maximum amount of protection and security for the community.

With respect to fluoride, again I'm not an expert, but it seems clear from a bit of reading, even to a layperson, that water fluoridation occurring at over 1 ppm is too much and potentially harmful whereas our current, naturally occurring fluoridation levels of 0.4 ppm is insufficient to provide our community with any oral health benefits. However, it sounds like the North American standard fluoridation level of 0.7 ppm strikes that necessary balance. Perhaps in the future the levels may require further adjusting but, as decision makers you can only be responsible for making decisions on the information before you and at this time the information from health authorities ~~right across the country states~~ that 0.7 ppm is an acceptable, safe level of water fluoridation that will provide oral health benefits.

It's my understanding that the upgrade to the infrastructure that will allow for the fluoride levels to be adjusted in the water will require several million dollars of spending. In our current economic situation I believe that this would be welcome spending by the community. The general community will feel the impacts of savings in dental costs that it will provide to each family, it's estimated that is somewhere between $1 and $135 for every dollar spent (Centre for Disease Control). And, the construction industry, the industry with which I am most familiar, could very much use an infrastructure project of this size, which would allow local general contractors, subcontractors, and suppliers to bid on every aspect of this project.

Finally, I know that some of you believe that as a public health issue this is beyond the city's jurisdiction. I agree that a much larger discussion on oral hygiene and public health must take place at some point but, until we have a government, either federally or provincially, that is willing to have that discussion, this is a step that most municipalities throughout North America believe to be within their power and is able to provide a positive impact to the oral health of young kids, as well as others.

And, I will add one last request, if you are uncertain of which direction the City should take then please, let the community decide. This has been put to a plebiscite numerous times in our City's history and the most recent removal was done without a clear mandate to do so. If Council is indecisive on this issue, then I respectfully request that you include this as a question on the ballot in 2021.

Thank you for listening to me today.

In response to Councillor's Woolleys question or comment regarding the downloading of costs associated to water fluoridation, I agree, perhaps the province is downloading the costs and perhaps it isn't fair. But, failing to act at the municipal level, essentially only downloads these costs to the parents and the children that cannot afford it. And, we know, that every dollar of investment in water fluoridation represents a return on investment of between $1 to $135 of savings.

Dear council members,

I am a 62-year-old retired family physician.
I have read documents for and against the fluoride topic, and have come to my personal decision:

I do not want fluoride added to our drinking water, now or ever!
My reasons are;

1. Fluoride is a chemical that would be added to our water - that has no proven benefits for health. Clean safe water means removing harmful substances FROM it, not adding unproven substances into it.
2. I believe we should be concerned about WHERE that fluoride comes from - The fluorosilicic acid that has been used is a substance captured from air pollution devices from the phosphate fertilizer industry, which would add other known toxins, including arsenic to our water.
3. There has been no decrease in carries in areas with fluoridated or with NON-fluoridated water. Perhaps the increase in caries that we are seeing has to do with other factors, not fluoride, that might be addressed
4. When added to our water, the dose each individual receives becomes an unknown. If fluoride becomes added to our drinking water, we are treating it like a drug, purposely added, for unproved benefits. It becomes completely unregulated in Dose received! It is absorbed thru the skin as well as the GI tract. Infants, elderly and sick people stand at increased risk for toxicity as they unknowingly ingest and absorb too much fluoride.

Sincerely,

Yvonne Heerema, MD, CCFP

October 23, 2019

Rick Woychik, PhD
Acting Director, National Institute of Environmental Health Sciences
P.O. Box 12233
Mail Drop B2-01
Durham, NC 27709

Gwen W. Collman, Ph.D.
Acting Deputy Director, National Institute of Environmental Health Sciences
P.O. Box 12233
Mail Drop B2-01
Durham, NC 27709

Dear Drs. Woychik and Collman,

Research supported by the National Institute of Environmental Health Sciences (NIEHS) has tremendous potential to expand scientific knowledge about human health and positively inform health and environmental policies. We write this letter regarding the NIEHS-funded Green et al study about maternal fluoride exposure; the article about this study was recently published by *JAMA Pediatrics*.[1] We have a variety of concerns about the Green article related to methodological transparency and analytical rigor. We wish to share these concerns with you and request that NIEHS formally ask the Green authors to release the HIPAA-compliant, Research Identifiable File (RIF) data sets from their study, as well as a complete explanation of their methods and the computer program/codes used in their data management and analysis.

In recent weeks, at least two of the Green authors have declined to respond affirmatively to requests from other researchers for access to the data and analytical methods they used. Growing concerns about the replicability of scientific research makes transparency more critical than ever. Recently, the editor-in-chief of the *Journal of Neuroscience Research* and nine other research experts wrote an article whose abstract opened with this observation: "Progress in basic and clinical research is slowed when researchers fail to provide a complete and accurate report of how a study was designed, executed, and the results analyzed."[2]

By releasing their raw data and a detailed explanation of their statistical methods, the Green authors could satisfy incongruities and ensure the scientific record is accurate. Given the potential policy implications of the Green article, we believe the authors should be more transparent, as this could provide clarity amid the concerns their article has raised. In recent weeks, a number of experts in epidemiology, psychology, statistical methodology and other fields have raised numerous concerns about the Green article, including the following:

1. **Focusing on a subgroup analysis amid "noisy data":** The Green authors focused a significant portion of their narrative on the one subgroup (boys) where a lower IQ association was observed, but only in the performance part of the IQ test. Thom Baguley, professor of experimental psychology at Nottingham Trent University, is one of several experts who have raised concern about this aspect of the article. "This is an example of subgroup analysis — which is frowned upon in these kinds of studies because it is nearly always possible to identify some subgroup which shows an effect if the data are noisy," he wrote. "Here the data are very noisy."[3] Part of the reason why the data are noisy is that the

Green authors included in their analysis IQ scores that fell within 2.5 standard deviations from the mean. In other words, only a very small number of scores could have been excluded, which explains why the study includes scores in the 50s, indicating profound delays, as well as scores in the 130s, which indicate giftedness. Not excluding extreme values or outliers may have skewed the regression analysis, the impact of which could be better understood with review of the raw data used by the Green authors.

Additionally, the Green article's focus on the subgroup analysis ignores the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations, which were issued more than a decade ago. The STROBE committee cited several reasons for these recommendations, including its view that "there is too great a tendency to look for evidence of subgroup-specific associations, or effect measure modification, when overall results appear to suggest little or no effect."[4]

2. **Modeling and variable anomalies:** As you know, a p-value indicates the probability that the results observed are by chance. In its Statistical Analyses section, the Green authors reported that they "retained a covariate in the model if its p-value was less than .20 or its inclusion changed the regression coefficient of the variable associated factor by more than 10% in any of the models." This could potentially be an example of p-hacking, meaning that variables are left in the model (or excluded) to achieve some sort of statistical significance in the final p-values.[5] In this regard, the authors did not explain why they chose .20 instead of .10 or .15 so readers of the article have no basis for deciding whether this decision was warranted or not.

Typically, when a researcher is testing associations between potential confounders and an outcome of interest, they set the significance level at $p<0.20$; however, for retaining them in the final model, they typically select only those with a significance of $p<0.05$. It is unclear if the Green researchers carried out this step. The more covariates that are included in the final model, the more likely it is that researchers will find a significant association.

One approach to account for the effects of including variables in the model as the Green authors did is to use Bonferroni's correction, something they do not appear to have done. Bonferroni's correction allows for the p-values of multiple comparisons to be performed at the same time in one model. Usually, this correction decreases the acceptable p-value at which a variable is considered to be statistically significant in its contribution to the observed statistic.

Further, the Green analysis failed to account for the influence of multi-level effects on the association between the independent and dependent variables or the multi-level effects such variables would have on the outcome of interest. Moreover, selecting the covariates in a stepwise manner has the potential to bias regression coefficients. Biostatisticians have discouraged the use of stepwise selection for this reason.[6] The American Statistical Association has established six principles on the use and analysis of p-values, one of which states: "Proper inference requires full reporting and transparency."[7] By releasing the data and a detailed explanation of their analytical methods, the Green authors would enable the scientific community to better assess whether their choice of p-value was appropriate.

3. **Lacking data on relevant factors:** In recent decades, studies have revealed numerous factors that can impact children's intelligence and cognitive ability. Parental behaviors and traits are among these factors; for example, research shows children's intelligence is linked to fathers' social class[8] and mothers' IQ scores.[9] Indeed, a 2013 study supported by the Centers for Disease Control and Prevention noted that these factors are "major predictors of IQ and should be included routinely in studies of cognitive development."[9] Unfortunately, the cohort on which the Green authors relied lacks data on maternal IQs and paternal social class. Although the Green authors had access to data on maternal lead exposure, the cohort provided no data on lead exposure for children during the 3-4 years between birth and their IQ

tests. This could be another confounder. The authors themselves acknowledge that "this observational study design could not address the possibility of other unmeasured residual confounding."[1] This is more than a minor concern, and it demonstrates why the Green findings should be interpreted with significant caution.

4. **Omitting crucial findings:** In the Key Points section of their article, the Green authors summarize the question their study sought to answer: "Is maternal fluoride exposure during pregnancy associated with childhood IQ in a Canadian cohort receiving optimally fluoridated water?" Nonetheless, the authors downplayed the lack of a statistically significant difference between children's mean IQ scores in fluoridated and non-fluoridated communities of Canada. Nowhere within the narrative of their article do they share the two mean IQ scores for the Full Scale IQ (FSIQ)—108.21 among children in fluoridated communities and 108.07 among children in non-fluoridated areas. These nearly identical scores could easily be missed unless readers carefully scan the 29 rows of data within Table 1. Instead, the Green article focused on the subgroup analysis where an association was observed. Contrast how the Green article reported its findings with how the authors of a 2018 article on lead exposures[10] presented their findings. Data for both articles was sourced from the same Canadian maternal-child cohort.[11] The authors of the 2018 article included three of the Green authors, and they summarized the results in their abstract in *Environment International* (EI) by leading with their primary objective:

> *"Median blood lead concentrations for the mother at 1st trimester and 3rd trimester of pregnancy, and for cord and child blood were 0.60 µg/dL, 0.58 µg/dL, 0.79 µg/dL and 0.67 µg/dL, respectively. We found no association between cord blood lead concentrations and WPPSI-III scores in multivariable analyses. However, cord blood lead concentrations showed a negative association with Performance IQ in boys but not in girls (B = 3.44; SE = 1.62; 95% CI: 0.82, 5.98). No associations were found between WPPSI-III scores and prenatal maternal blood or concurrent child blood lead concentrations."*

By stark contrast, the Green authors proceeded to their subgroup analyses without mentioning the full-scale IQ scores for fluoridated and non-fluoridated areas. Additionally, they did not report the main effect result for maternal urinary fluoride (MUF) and IQ.[12] Had the Green authors reported the main effect result, it would have shown the association between MUF and IQ was non-significant—both with and without covariates. STROBE guidelines indicate that all main effect results should be reported (Guideline #16), in addition to any interactions and sensitivity analyses (Guideline #17).[4]

5. **Using invalid measures to determine individual exposures:** According to an article coauthored by the director of Columbia University's Applied Statistics Center, *the* most important assumption in linear regression is that the independent and dependent variables map to one's research question and are valid.[13] In this case, relying on MUF and a twice-administered beverage recall question estimating types of fluid consumption are not reliable ways to determine fetal fluoride exposure. Moreover, relying on these measures could threaten construct validity, a limitation which is not adequately discussed by the authors. This issue is compounded by the fact that MUF was gathered by spot urine samples rather than 24-hour samples. Alastair Hay, professor emeritus of environmental toxicology at the University of Leeds, reviewed the Green article and raised this concern: "For a substance with a short half-life, such as fluoride, urine concentrations vary hugely and are really only representative of the last drink. Validation of intake is something you must do before looking at associations."[3]

Researchers have noted the limitations of extrapolation from urine samples, observing that "daily urinary fluoride excretion is suitable for predicting fluoride intake for groups of people, but not for individuals."

In their assessment: "Thus, it can be concluded that, at this time, urinary fluoride excretion has a very limited value as a biomarker of individual fluoride exposure."[14] Dr. F. Perry Wilson, a nephrologist at the Yale School of Medicine, criticized the Green article for relying on urine samples "because urine fluoride is not a perfect proxy for blood fluoride." Moreover, Dr. Wilson identified a new variable that the authors introduced:

> *"... more dilute urine will have a lower fluoride concentration, and they 'correct' this problem by dividing urinary fluoride by urine specific gravity. But this introduces a new variable. Assuming that fluoride has no effect on a child's IQ, you could get results that look like this if moms with more dilute urine tend to have kids with lower IQs."*

Dr. Wilson also noted that the article's results could have been skewed because women with a higher urinary pH (due to diet or other factors) tend to have higher urinary fluoride levels.[15]

6. **Defining the final study group:** The Green study is not representative of all mothers and their children in Canada, and, therefore, not generalizable. This is clear from Figure 1 in the Green article, indicating that a significant number of mother-child pairs were excluded from the final study group.[1] The cohort was drawn from six cities, and the authors did not account for clusters of sampled pregnant women or consider multilevel models. It is not entirely clear from the Figure 1 schematic or the article's narrative why all of these pairs were excluded, and it is important to learn the authors' reasons for exclusion to understand fully the actual fluoride exposure and its effects on IQ scores. What we do know is that some of the pairs were excluded because they did not drink tap water or lived outside a water treatment zone.

This kind of exclusion would make sense only if the authors were specifically seeking to compare IQ scores based on water fluoridation status, but they did not present their results in this way. The authors should have been more explicit as to the reasons for excluding the mother-child pairs that they removed from the final study group. The fact that the association was observed only in boys could be an artifact of who was left out of the study and how the Green authors modeled sex in the regression.

7. **Assessing the impact of fluoride exposure:** Several questions arise because the details of the regression model used by the Green authors are not provided. Further, the authors assessed daily fluoride intake in mothers using a non-validated questionnaire, and their estimates of fluoride intake based on water and tea consumption appear to be crude. The narrow focus on tea-drinkers could have biased the results by overlooking other sources of fluoride intake. In this regard, the EI article (cited previously) on prenatal lead concentrations and IQs in this same cohort are instructive. The EI article demonstrated that cord blood lead level was associated with IQ in boys in this cohort (but not girls). While the supplemental table eTable 2 of *JAMA Pediatrics* shows that controlling for lead does not alter the predictor or its standard error, it does raise questions about the role of environmental lead in this cohort. Additional information concerning the measure of lead exposure in the Green study's sensitivity analysis is needed, especially given research showing that blood lead levels are higher in those who drink tap water.[16] Release of the RIF data and a detailed explanation of the modeling used by the Green authors would be valuable for clarifying the relationship among these variables.

8. **Reporting anomalies:** The authors reported that a 1 mg/L increase in the adjusted MUF concentration was associated with a 4.49-point lower IQ score in boys, but there was no statistically significant association with IQ scores in girls ($B = 2.40$; 95% CI, -2.53 to 7.33). And a 1 mg/L higher daily intake of maternal fluoride was associated with a 3.66 lower IQ score in boys and girls. The Green authors did not discuss the magnitude of change in the sex differences for IQ observed in the MUF-adjusted regression.

This difference includes an actual sign change between boys and girls (from - to +) that poses a significant threat to the validity of their results. Instead, the authors stressed the results for boys while ignoring the disconnect between boys' performance IQ and verbal IQ scores. Also unmentioned in the Green article is the overlapping confidence intervals throughout for boys and girls (see Table 2), which means there is a greater than 5% probability that the IQ measurements for boys and girls are actually *not* different from each other.

In addition, while several covariates have been found in the past to be significant determinants of IQ score and are not included in the Green study, the reported 95% confidence interval (CI) in boys (−8.38 to −0.60) is too wide to be statistically acceptable. The ordinary multivariable statistical methodology (e.g. regression analysis adjustment) used in this study, which is indeed widely known and used in epidemiology, focuses on the association with the outcome.[17] However, this kind of analysis does not adequately address complicated problems, where measured and unmeasured confounding is involved.[18,19] Alternatively, novel methodological approaches (e.g. propensity scores and Inverse Probability Weighting) are being used in the medical, epidemiological and biostatistical research to infer causal effects with less potential bias and to provide narrow and more precise CIs.[20,21,22] The 95% CI in this study for boys' IQs reveals that this score can have a value of .6, which is almost 15 times smaller than the higher value (8.38) estimated in this interval. The study's omission of significant predictors/confounders (see #3) for IQ scores resulted in this wide interval, limiting the validity of the results.

9. **Internal inconsistency of outcomes:** The Green authors reported the overall effect result for fluoride intake (FI) in this way: "A 1-mg higher daily intake of fluoride among pregnant women was associated with a 3.66 lower IQ score (95%CI, −7.16 to −0.15; P = .04) in boys and girls."[1] An attentive reader would recall that the association found in the MUF regression was not all children; rather, boys showed an associated decline on one part of the IQ test, but girls did not. (In fact, girls had an observed increase in IQ.) Here, the authors attempted to demonstrate internal consistency of analysis outcomes for both FI and MUF. In summary, they observed the FI intake effect when they combined boys and girls (overall effect), but they found the effect of MUF only in boys. Additionally, Green did not find an effect with FI in her thesis when she included the same covariates.[23] Had the Green authors reported this lack of association in the *JAMA Pediatrics* article, it would have been strong evidence of internal inconsistency.

Upon closer comparison, the Green thesis states they excluded city as a covariate to achieve statistical significance for the FI analysis. As the Green thesis explained (p. 34): "Holding all covariates constant, FI significantly predicted [Full-Scale IQ] scores **without city** in the model (B = -4.03, 95% CI: -6.82 to -1.25, p = .005*) (Figure 6). **With city** in the model, FI just missed significance (B = -3.82, 95% CI: -7.65 to 0.02, p = .05). In both models, there were no significant interactions between FI and any of the covariates" (emphasis added).[23] By contrast, in the *JAMA Pediatrics* article, Table 2 reported that FI was adjusted "for city, HOME score, maternal education, race/ethnicity, child sex, *and* prenatal secondhand smoke exposure."[1] However, these two model outputs, 3.82 in the thesis versus 3.66 in the article, are different. Allowing the raw data to be reviewed and analyzed might reveal exactly how the researchers managed to find a model with significant effect with city for inclusion in the article. Accordingly, Dr. Stuart Ritchie of the Institute of Psychiatry, Psychology and Neuroscience at King's College London, reinforced this point in his recent comments about the second analysis, which was FI:

> *"For the second analysis, where there's an overall effect, the p-value is .04—that is, it's JUST below the standard threshold used for declaring something to be significant (0.05). Given that they ran lots of other hypothesis tests in the paper, and didn't correct*

for how many times they did so, I wouldn't have much confidence in this finding being robust or replicable" (capitalization in original).[3]

It could be that the authors were able to achieve a significant effect in the FI analysis with city in the FI model because they included secondhand smoke as another covariate. This possibility presents a significant problem because the number of smokers in the Green sample of 400 is only 11. In the EI article that studied the same cohort, the authors specifically stated that they excluded the secondhand smoke exposure variable from the analysis because of the lack of variance.[10] It is possible that without the secondhand smoke variable in the FI model, the two main effect models MUF-IQ and FI-IQ would show no association. This undermines the main discussion point in the Green article that there is a "converging" of the two analyses. In fact, the two models might be remarkably similar in showing no effect of fluoride on IQ. To clarify these discrepancies, the scientific community needs to have access to the Green data sets so they can be reanalyzed using a multi-level model—or, at the least, a principled accounting for the design effect arising from cluster sampling, and adjusting the p value for multiple hypothesis testing. Such an independent analysis could help us determine whether fluoride exposure at common levels has an effect on IQ in this cohort.

10. **Overlooking research that conflicts with the authors' conclusions:** Typically, when researchers identify their study's limitations in the Discussion section, they acknowledge other research that reached different conclusions and perhaps consider possible explanations for these differences. Yet the Green authors do not acknowledge or cite several studies about fluoride and cognitive development, including one that (unlike their study) tested IQs multiple times over a 30-year period.[24,25] Although most of these studies did not focus on maternal exposures, one such study, co-led by researchers at the National Toxicology Program (NTP), examined animal exposures to fluoride during the gestational period and observed no exposure-related differences in learning skills or memory.[26] Although the NTP-led study was cited in the Green article, the authors did not mention the NTP study's conclusions. Of related concern, the Green article's citations are limited in scope and include three articles from Fluoride, a publication that has been described as not applying a high degree of rigor when publishing studies.[27] Altogether, these concerns suggest the Green authors may have conducted a selective literature search that could reflect a predetermined conclusion.

Summary and Requests

We believe the Green authors should have taken additional steps to address or at least fully acknowledge potential confounders. Moreover, they should have presented their findings in a more transparent, qualified way that reflects STROBE guidelines. Given that the NIEHS funding award was an R21 exploratory grant, the authors should have exercised more caution in the interpretation of the results.

The publication of this article in a mainstream, peer-reviewed medical journal has generated a tremendous amount of media coverage. If the Green authors had merely called for more research, our focus would be directed toward ensuring that future research in this area is more methodologically robust and reflective of STROBE guidelines. However, the article's release was followed by statements to major media by the journal's editor[28] and at least one author that are creating confusion, shaping individual behaviors and influencing public policy. For instance, the corresponding author of the Green article told *Time* magazine that instructing pregnant women to reduce their fluoride intake is "a no-brainer."[29] The fallout from the Green article is currently most visible in the Canadian city of Calgary, where the article is being cited as a reason not to resume water fluoridation after eight years of cessation and significant increases in tooth decay.[30]

The aim of science is to gain a better understanding of our natural world and to build a shared knowledge base for the benefit of all. Every scientist is interested in the truth. If fluoride at common levels of maternal exposure does lead to lower IQ scores, we would certainly want to know. This is why transparency related to the Green article is crucial. Given the concerns outlined herein:

- We urge NIEHS to ask the Green authors to release their RIF data set and provide a thorough explanation of their analytical methods. Doing so could enable an independent review that would bring clarity and ensure the scientific record is accurate.
- Should the Green researchers not voluntarily release their data, please advise us on what the process would be to have the data set released so an independent analysis of the Green data can be conducted.

Without greater transparency of its data and analytical methods, the Green article could generate unjustified fear that undermines evidence-based clinical and public health practices. So much is at stake. Hundreds of millions of people around the globe—from Brazil to Australia—live in homes that receive fluoridated drinking water. Hundreds of millions of people use toothpaste or other products with fluoride. Many millions of children receive topical fluoride treatments in clinical or other settings. Tooth decay remains one of the most common chronic diseases for children and teens, and fluoride is a crucial weapon against this disease. Decay prevalence could increase if a journal article unnecessarily frightens people to avoid water, toothpaste or other products fortified with fluoride.

Please let us know if you have any questions about our request or the issues raised in this letter. Please consider Dr. Scott Tomar (stomar@dental.ufl.edu) as the individual to whom you can direct your response. We greatly appreciate your time and consideration.

Sincerely,

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Chair, Global Child Dental Fund
Former Chief Dental Officer for England

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Chair, Platform for Better Oral Health in Europe
Chair of the Royal Society for Public Health

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New and Emerging Issues Committee
Expert Body on Fluorides & Health, Ireland

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Bloomberg School of Public Health
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H. Grant Ritchey Jr., DDS, FAGD
Practicing dentist in Kansas, contributor to
Science-Based Medicine blog

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Prevention
Consultant, Dental Public Health
President, European Association of Dental
Public Health

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University of Iowa College of Dentistry

CC: Patrick Breysse, PhD
Director, National Center for Environmental Health (CDC)

Karen Hacker
Director, National Center for Chronic Disease Prevention and Health Promotion (CDC)

Martha J. Somerman, DDS, PhD
Director, National Institute of Dental and Craniofacial Research

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Health Canada / Santé Canada

Access to Information and Privacy Division
7th Floor, Suite 700, Holland Cross, Tower B
1600 Scott Street
Address Locator: 3107A
Ottawa, Ontario K1A 0K9

Our file: A-2014-00168/ na

May 26, 2014

<address snipped>

Dear ....

This is in response to your request under the *Access to Information Act* (the *Act*) for: **Clarified Request Text:**
Reports, studies, toxicology and clinical tests relating to hydrofluosilicic acid in Canadian tap water

Original Request Text:
Documents pertaining specifically to hydrofluosilicic acid in Alberta and Canadian tap water:
- Studies from 1940 showing dental efficacy and human safety.
- Studies from 1950s showing dental efficacy and human safety.
- Any double blind study done by Canada or any province showing dental efficacy and human safety, of any date.
- Any double blind study done by anywhere in the world that was considered.
- Any toxicity study, of any date, done by Canada or the world that was considered.
- Evidence of any kind (not opinion) that shows statistical viability of water fluoridation in terms of efficacy, and margin of error calculations.
- Evidence of any kind (not opinion) that shows statistical viability of water fluoridation in terms of human safety over a life-time, and margin of error calculations.
- Evidence of any kind (not opinion) that shows statistical viability of water fluoridation in terms of human safety, and margin of error calculations, for infants, young children, elderly, or any adult with disability, diabetes, bone disease, autism, thyroid ailments, kidney disease, etc.
- Evidence of any kind of consideration of human rights and medical ethics, namely our human right to opt out of the forced water fluoridation program, and if that consideration exists, why the overriding of these well-established medical standards are breached.

After a thorough search for the requested information, no records were located which respond to your request.

If you have any questions or concerns about the processing of your request, please do not hesitate to contact Nancy Armstrong, the analyst responsible for this request, either by phone at (613) 960-4457, or by fax at (613) 941-4541, or by e-mail at nancy.armstrong@hc-sc.gc.ca with reference to the file number cited above.

Canada

For the record my name is Arthur Matsui (m a t s u i) and I have read the O'Brien report and many other fluoride studies and I do not consent to the addition of fluoride to Calgary's water supply. I also hereby revoke any consent for water fluoridation implied, or otherwise that may be attached to my Name.

I am a longtime Calgary taxpayer and have voted in every election on three levels of government since 1974. I am a third generation Japanese Canadian whose family's rights were stripped due to our racial background and am sensitive to the protection of my rights.

The Canadian Dental Association (CDA), the Canadian Medical Association (CMA) and United Nations Educational, Scientific and Cultural Organization (UNESCO) all agree that before any treatment is permitted, the patient has the right to be informed and must give their informed consent. The **O'Brien report** (pages 30, 31, 32) identifies "A key ethical/legal issue related to community water fluoridation programs centres around individual autonomy and the ability to make personal health-related decisions." and "Furthermore, it should be noted that it is particularly challenging to individually opt out of water fluoridation"

Water fluoridation is a treatment that the City of Calgary is examining to re-introduce in the hopes of preventing dental caries but as you have heard today there are also many potential harmful side effects. Fluoride intake through fluoridated water is uncontrollable to dosage, since people are receiving varying doses according to their water intake and exposure to other sources of fluoride. According to the 2006 National Research Council's Review, 1-12 years old children's average intake of fluoride from pesticides, air and food is equivalent to the amount they receive from fluoridated drinking water. Again that is only an average, individuals can receive a higher dosage or be more sensitive to fluoride's un wanted effects. Before adding a toxic substance like fluoride to the community's drinking water, it is the City's responsibility to prove Fluoride's unequivocal safety, which they cannot do as they have no control over dosage of the individual and other methods of delivery must be found should they insist on fluoridating Calgarians.

In 2016, the Fluoride Action Network (FAN) and coalition partners filed a petition asking the EPA to ban the deliberate addition of fluoridating chemicals to U.S. drinking water under Section 21 of the Toxic Substances Control Act (TSCA). Despite the EPA's five legal challenges to this case, it will be heard in February 2020. Should they win this case, it will set the precedent that forces communities to remove water fluoridation as an option.

As was stated recently in council the duty of Council is to keep the community viable and safe, and should they knowingly legislate something that affects the viability and safety of the community they will be liable. Water fluoridation is a therapeutic medical intervention by the City of Calgary to which I do NOT consent and to opt out should the City go forward would be of considerable cost and expense to myself and other Calgarians. To that end, should a water fluoridation initiative go forward to Calgary City Council, I reserve the right to submit my fee schedule at that time.

In 2011 when fluoride was removed, new fluoridation equipment was to cost $6 million and the cost of the Hexafluorosilicic acid was to cost $1 million a year. As a taxpayer it seems to me that the costs and ancillary costs of fluoridation are un-warrranted in these times of budgetary shortfall.

Canadian Dental Association - Code of Ethics

Respect for autonomy

Respect the patient's right to choose; patients have **the right to be fully informed and make choices** for, and actively participate in, their care and pursue their personal values, beliefs and goals in achieving their optimal oral health.

Canadian Medical Association - Code of Ethics

11. **Empower the patient to make informed decisions** regarding their health by communicating with and helping the patient(or, where appropriate, their substitute decision-maker) navigate reasonable therapeutic options to determine the best course of action consistent with their goals of care; communicate with and help the patient assess material risks and benefits **before consenting to any treatment** or intervention.

12. **Respect the decisions of the competent patient to** accept or **reject any** recommended assessment, **treatment**, or plan of care

United Nations Educational, Scientific and Cultural Organization

"**Any** preventive, diagnostic and **therapeutic medical intervention is only to be carried out with the prior**, free and **informed consent** of the person concerned, based on adequate information. **The consent should**, where appropriate, **be express and may be withdrawn** by the person concerned **at any time** and for any reason **without disadvantage or prejudice."**

- *UNESCO on Medical Consent in Bioethics and Human Rights, Article 6 (2005)*

"**In no case should** a collective community agreement or **the consent of a community leader or other authority substitute for an individual's informed consent**."

- *UNESCO documents on Medical Consent in Bioethics and Human Rights, Article 6 (2010)*

O'Brien report (pages 30, 31, 32)

A key ethical/legal issue related to community water fluoridation programs centres around **individual autonomy and the ability to make personal health-related decisions.**

Furthermore, it should be noted that it is **particularly challenging to individually opt out of water fluoridation.**

"It is difficult to get a man to understand something, when his salary depends on his not understanding it."

Thank you so much for the opportunity to speak on this critical issue

If this passes, we're going to spend $7-10 million "putting the burden on the backs of Calgary taxpayers" to purchase, hire & train staff, and install equipment to administer a toxic waste product to drinking water violating ethics to medicate Calgarians without obtaining **informed consent** of every individual.

ON and FOR the record – I do not CONSENT

➔Any benefit of fluoride is excruciatingly negligible and only reported affect on the teeth is though topical applications and not swallowing – so, what, then is the purpose of it in water?

> * Our enamel is much thinner than originally believed, and the topical effect of fluoride on enamel is much less than originally thought. This is one of the PUBMED publications that supports that discovery.

- ➔ LARGEST PUBLICATION OF IT'S KIND nearly 500 pages, - a REVIEW of the EPA fluoride standards, prepared by the NRC reports levels in different body tissues in fluoridated areas.
- We know it's only a topical effect, right? So how much fluoride in saliva? The chart shows ➔ where there is .8ppm in water,
- ➔ Ave F content in saliva was only .011ppm [what a waste of money if topical fluoride is indeed the goal]
- ➔ However there is 1000- 1500 +++ ppm toothpaste – representing 91,000 – 136,000 more F contacting the teeth than from drinking F water.
- ➔ Toothpaste is CHEAP – this week at COSTCO you can get a 5 pack - tubes bigger than this for $10 – if a family of 4 spends more than $30 a year, they're taking in too much

3 The actual industrial waste product cities pay to consume relieves industry of their burden to pay for disposal. Why wouldn't they be compelled to obtain endorsements. Industry and government agencies were wrong and deceitful about thalidomide, VIOXX, oxycodine, cannabis, saturated fat, let's not also be on the wrong side of the fluoride issue.

CALGARY – WE HAVE MORE TO LOSE BY BEING WRONG ABOUT SUPPORTING FLUORIDATION THAN WE HAVE TO GAIN BY BEING RIGHT!

If fluoride is reintroduced, thousands will buy bottled water increasing our plastic consumption. ***"What would Greta say?"***

I've spoken to micro breweries, they're very concerned about the costs to remove fluoride, and damage to their equipment.

I know many are here citing their own experiences, blaming lack of fluoride in water for their poor dental health.

Here's my experience, ~~but I'm RARE, small and shrinking sample of ONE.~~

I grew up in a small City in SK that was not fluoridated, I drank raw milk, I hated sugar and sweets, I loved meat, and didn't much care for vegetables. I hated soda pop, I didn't like water, I didn't like juice. I hated candy, I would taste it once in a while in an attempt to understand the appeal.

I was raised in a Doomsday cult, we did not celebrate Christmas, Easter, Hallowe'en, birthdays or tooth fairies, all key events which typically provide opportunities for a great deal of sugar consumption.

I never had any cavities. When teams of dental students were sent out by the university, my parents would respond with DO NOT consent regarding their fluoride and "free" dental treatment (there were reports of injuries and errors)
Mom's Teeth + she ♡s sugar
Honestly my first dentist appointment was at the age of 16, he laughed and instructed his assistant to bring in my father from the waiting room, showed him my teeth with that little mirror and sent us home telling us to keep doing what we were doing. His son was my classmate, who, he said, had terrible teeth.

~~*** I DO NOT CONSENT ***~~

Instead of a motion to put it in water, we should have a motion to warn people about it.

- City of Calgary tells us not to put pollutants in the storm sewers. PIC

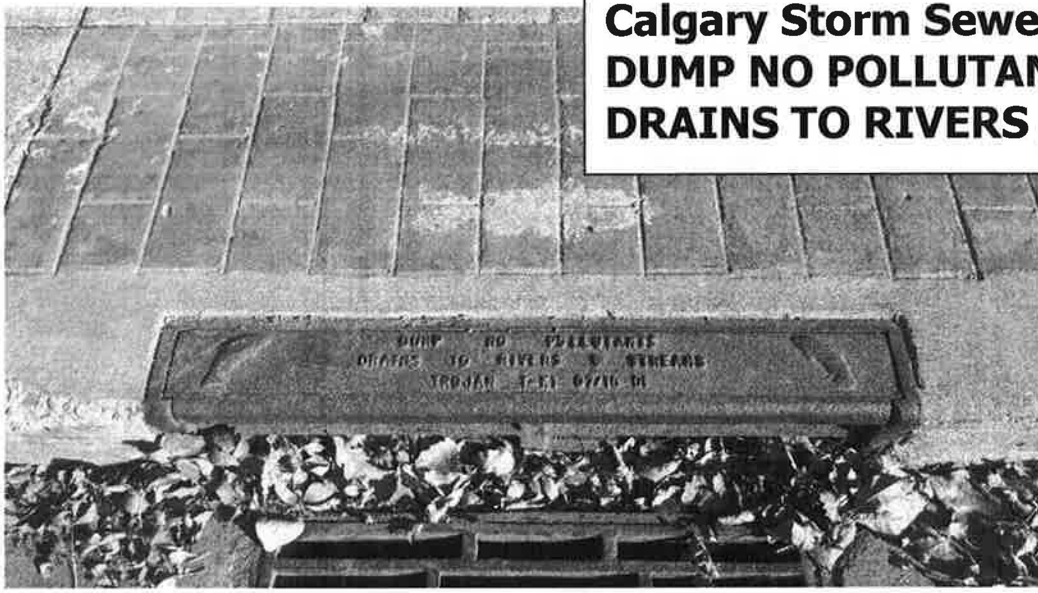
- Yet a toxic waste product is going to be purchased for our water – here's a news report out of Utah earlier this year, hundreds were sickened when a pump malfunctioned, releasing undiluted fluoride, "a hazardous, poisonous material, also containing arsenic, lead, copper, manganese, iron and aluminum'

- An option product out of china caused some issues in a US municipality, package package label reads "Target Organs, Heart, Kidney, Bones CNS, GI, Teeth, Do Not Get In Eyes Or On Skin, Do Not Ingest Or Inhale

- Pharmaceutical Grade? – toothpaste

- Lab Grade, too expensive for the millions of liters needed for our water. Highly dangerous, that if one spills it on themselves, they are to ➔ Flush/wash area immediately, Apply gel continuously WHILE seeking medical attention

- This a news article about an accident where a truck hauling fluoride to Kingston crashed, driver died because the fluoride totes broke through cab, spilled on him, and the company got fined a total of $312,500 for injury and for the environmental damage.



Calgary Storm Sewer reads:
DUMP NO POLLUTANTS
DRAINS TO RIVERS AND STREAMS

ksl.com/article/46536380/report-shows-239-people-sickened-in-utah-fluoride-overfeed-investigation-conti

KSL.com News Sports Brandview TV Radio Live Obituaries Weather 36°

Pump malfunction = accidental release into drinking water in Utah on Feb5, 2019

"The concentrate in its undiluted form is classified as a hazardous, poisonous material that, while it contains fluoride, also contains arsenic, lead, copper, manganese, iron and aluminum."

Report shows 239 people sickened in Utah fluoride overfeed; investigation continuing

By Amy Joi O'Donoghue, KSL | Posted - Apr 21st, 2019 @ 1:46pm

98

SANDY — A state-required report documenting the health impacts of an accidental release of fluoride concentrate in Sandy said there were 239 cases of human exposure in which people experienced gastrointestinal symptoms such as vomiting and headaches.

That number is substantially higher than early reports of the Feb. 5 incident, which sent undiluted hydrofluorosilicic acid from a malfunctioning pump into part of the city's drinking water system, affecting 1,500 households, schools and businesses.

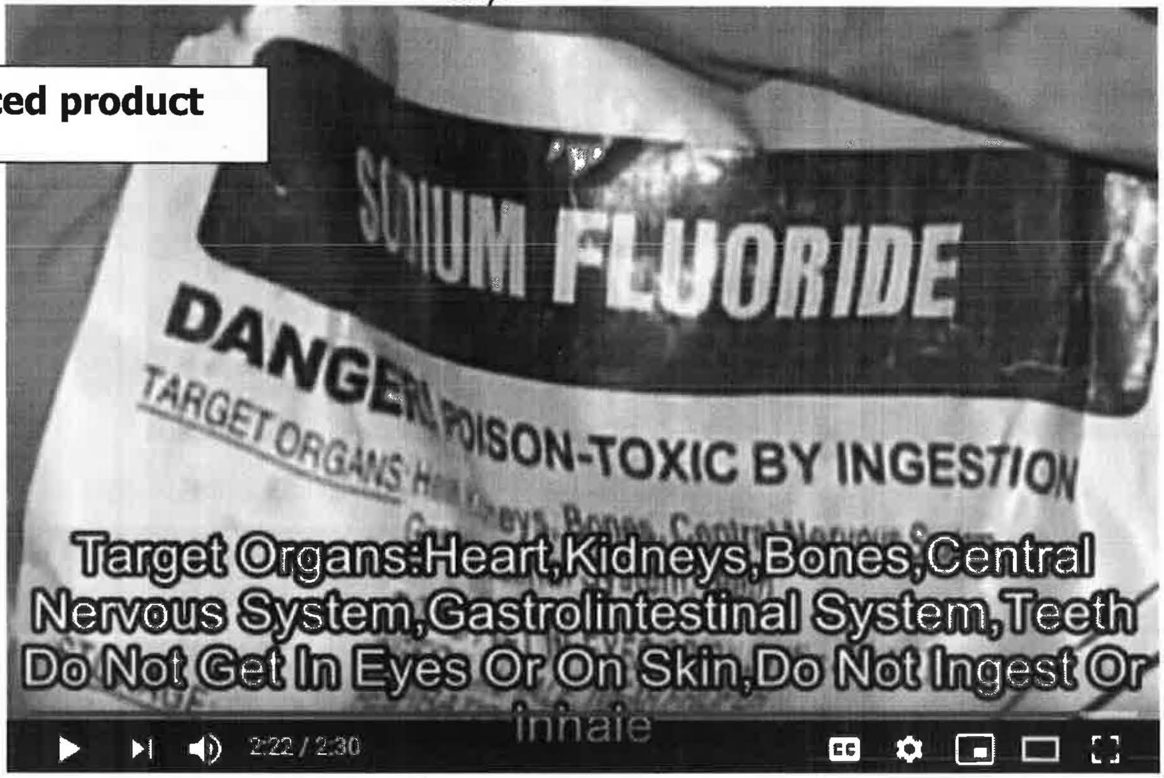
The concentrate in its undiluted form is classified as a hazardous, poisonous material that, while it contains fluoride, also contains arsenic, lead, copper, manganese, iron and aluminum. It is a byproduct from phosphate mining operations.

Fluoride was detected at 40 times the federal limit after the release, and two weeks of free blood testing for lead showed one person with elevated levels, according to Salt Lake County health officials.

The release happened as a result of a power surge during a snowstorm.

Image captured from a US TV news item, about town that ceased fluoridation due to concerns about the product they were using from China. How ironic, really, considering the other source, the waste from the fertilizer industry.

China sourced product

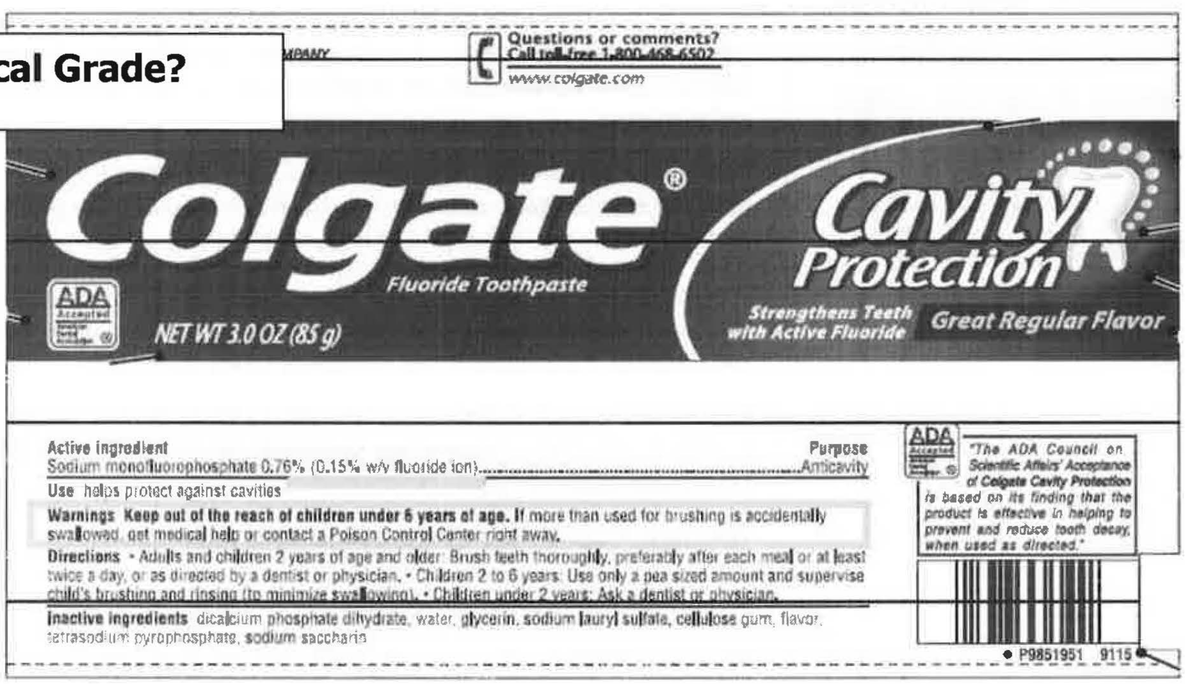


US Colgate label – 1500 ppm

WARNINGS: Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally ingested, get medical help or contact Poison Control Centre right away.

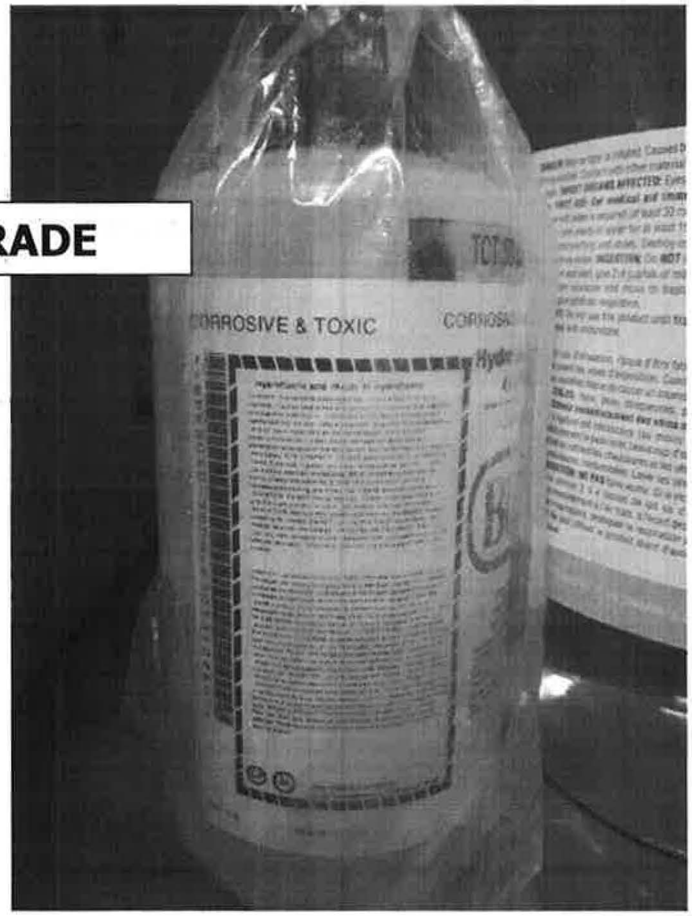
= water fluoridation is an unnecessary expense as toothpaste is hundreds of thousands of times more fluoride than water

Pharmaceutical Grade?

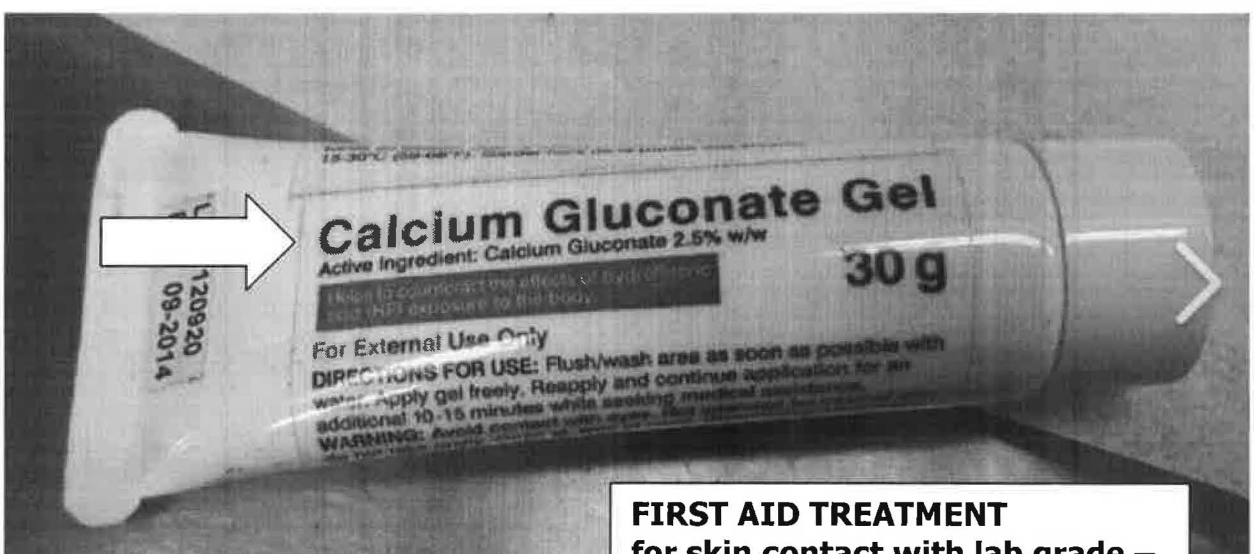


LAB GRADE - Hydrofluoric Acid used by Calgary based metallurgical engineering firm. This is a much more expensive product, and very dangerous though not the toxic waste product used for municipal water treatment.

LAB GRADE

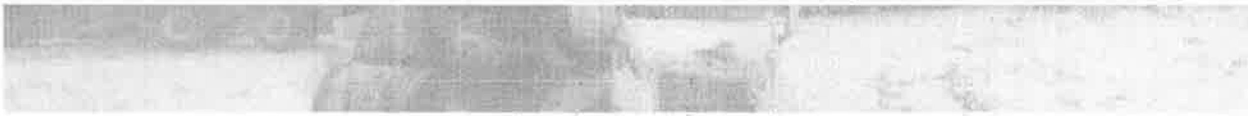


FIRST AID TREATMEMT for above:
Label reads: Flush/wash area as soon as possible with water. Apply gel freely. Reapply and continue application <u>WHILE seeking medical attention</u>.



FIRST AID TREATMENT
for skin contact with lab grade – Hydrofluoric acid

More than $300,000 fines to trucking company for the environmental contamination in ON caused when their truck driver crashed, scattering totes of fluoride being sent to Kingston for water treatment. Many broke and spilled onto to ground. Truck driver died of injuries due to contact with fluoride, many first responders were injured, the first one on the scene the most critical http://hazmatmag.com/2019/02/ontario-trucking-company-fined-250000-over-hazmat-incident/



Ontario: Trucking Company Fined $250,000 over hazmat incident

February 27, 2019 / 0 Comments / In HazMat, News, Trending / by John Nicholson

Titanium Trucking Services Inc., headquartered in Ontario, was recently convicted of one violation under the Ontario Environmental Protection Act and was fined $250,000 plus a victim fine surcharge of $62,500 and was given 24 months to pay the fine. Luckily, no one was h The fine was the result of a hazmat incident in which a fluorosilicic acid spilled from a tanker truck into the natural environment, which caused adverse effects. No one can predict anything like this to happen, which is why it is important to always stay focused on the road no matter what vehicle you drive. Luckily no one was hurt in this collision. Saying this though, if you have been involved in a trucking accident and were not sure what to do next, getting some assistance from a personal injury lawyer springfield il could be the answer you need that can help you get your life back on track after this incident. There's nothing wrong in asking for help.

Fluorosilicic acid is corrosive and causes burns. It decomposes when heated, with possible emanation of toxic hydrofluoric acid vapours. It is used in fluoridating water and in aluminum production. In the aquatic environment, an accidental spillage of fluorosilic acid would suddenly reduce pH level due to the product's acidic properties.

At the time of the offence, Titanium Trucking Services Inc., which is located in Bolton (just northwest of Toronto) had a contract with a Burlington, Ontario area chemical company to provide drivers and vehicles on a dedicated basis for chemical product transportation.

In January 2017, the Burlington area chemical company placed an order for 81,000 kg of 37-42% fluorosilicic acid, which was required for pickup in Montreal for transport to Burlington. Fluorosilicic acid is a corrosive liquid, classified as a dangerous good.

On the date of the planned chemical pick-up, Environment Canada had issued weather advisories relating to a major winter storm and the public was instructed to consider postponing non-essential travel.

The chemical pick-up occurred as planned on March 14, 2017, and within four hours after leaving Montreal, the truck and the driver were involved in a multi-vehicle collision while traveling westbound on Highway 401. As a result of the collision 15 totes of fluorosilicic acid ejected through the front wall of the trailer and also came to rest in the roadside ditch.

March 14, 2017 incident on Highway 401 near Mallorytown. Several first responders were exposed and needed to be decontaminated. (XBR Traffic)

The acid discharge caused further adverse effects, a total of 13 First responders and another sixteen members of the public had to be decontaminated, the 401 highway was closed in both directions, and the OPP officer who initially attempted to extract the truck driver from the cab on scene experienced significant health effects. In addition, adverse impacts to the roadside soil ecosystem occurred.

Tags: environmental charges, environmental fine, hazmat, hazmat incident, spill

Also: https://www.therecord.com/news-story/7189833-one-dead-after-multiple-transport-collision-chemical-spill-on-highway-401/

https://news.ontario.ca/ene/en/2019/01/trucking-company-fined-250000-for-ontario-water-resources-act-violation.html ETC.

From a chart provided in National Research Council's (NRC) 467 page report chart page 58

FLUORIDE IN DRINKING WATER: A Scientific Review of EPA's Standards

https://www.actionpa.org/fluoride/nrc/NRC-2006.pdf

When avg. F content in H2O was = .8 ppm

Ave F content in saliva was ONLY .011 ppm

?Where does the rest go?
soft tissue?
brains?
bones?
urine (50%)

ALL CO$T + = no benefit

1000 – 1500 **+** ppm**
= 91,000 – 136,000 x
more F in toothpaste than in saliva with "chronic" F H20 use.

Toothpaste is CHEAP!!!
If a family of 4 spends more than $30 on toothpaste for a YEAR, they're probably ingesting too much poison that does not even do what it's been promised to!

https://www.actionpa.org/fluoride/nrc/NRC-2006.pdf

"It is difficult to get a man to understand something, when his salary depends on his not understanding it." Upton Sinclair https://www.ncbi.nlm.nih.gov/pubmed/21090577

Elemental depth profiling of fluoridated hydroxyapatite: saving your dentition by the skin of your teeth?

In both cases, however, the fluoridation affects the surface only on the nanometer scale, which is in contrast to recent literature with respect to XPS analysis on dental fluoridation, where depth profiles of F extending to several micrometers were reported.
In both cases, however, the fluoridation affects the surface only on the nanometer scale, which is in contrast to recent literature with respect to XPS analysis on dental fluoridation, where depth profiles of F extending to several micrometers were reported.

topical only (not ingestion)
enamel is only 6nm (miniscule)

Only a nano-layer of your tooth absorbs fluoride, from surface contact, new research shows. Not only does **fluoride not reduce tooth decay by being swallowed, it may not even help by brushing it on the surface**, it now appears.
The research shows the layer is up to 100 times thinner than previously estimated - only 6 nanometres. That is 1/10,000th the width of a human hair. Such a thin layer is quickly worn off by normal chewing. The question has to be asked "how can this have any effect on tooth decay?," the researchers query.

Fluoride, leave me alone!

Shaoli Wang wangshaoli@yahoo.ca 587 889 0985

1. My name is Shaoli Wang, I'm a geologist. I do not use toothpaste for over 15 years, and that option stays with me only. My wife uses it daily, and her background is supposedly to be challenging to me, but she did not. Still, I stand here, represent myself only. My wife's background is dentist and she used to have her own dental clinic back home.

There were brief conversations about toothpaste, but no argument between us in that regard.

2. More often than not, we felt been discriminated against based on our belief or value, we felt offended, victimized, bullied, but were ultimately defenseless.

I tell you why.

CANADIAN CHARTER OF RIGHTS AND FREEDOMS

15. (1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability,

The law looks simple and clear, reasonable and logical, but was practically misunderstood from the day it was signed into our constitution in 1982. It has been misinterpreted as protecting confined rights not unconfined rights, and is therefore despisable in this regard.

The very wording under my fire is "In particular". It does not mean "exclusively", but it was practically misinterpreted as "exclusively".

3. According to the actual meaning of Section 15 of our Charter Rights and Freedoms, nobody has the rights to force anything into my mouth, no group of people can legitimately assume the rights to vote anything into my mouth without my knowing consent, which would otherwise be discrimination based on belief and value which were protected under Section 15(1).

We had this beautiful Peace Bridge built, no less notorious than its beauty is its appalling cost.

We had this wasteful Olympic bid voted a while ago. 56.4% say no to our servants.

We have this ever-growing property tax which has been there for so long and everyone seems to have been so numb that we can be knowingly robbed more and more at our failed servants' will.

While, there might not be arguments if I say fluoride is far more controversial than those topics. But, there is little idea how much it could benefit people's teeth, even less idea how much it might negatively affect people's health other than teeth, the passion to help people in need is well respected.

4. Bottom line, you don't force anything into my mouth, cost-free or not. Even a very experienced doctor like Dr. Dickson might not assume the power to do that, and I bet, what he is standing for is based on his knowledge and dedicated research, for sure, but more importantly, which I would confidently believe, is motivated by his morality which is less seen in our modern society.

5. I personally would not like to see any more debate regarding this topic in this Hall again because of serious concerns that every Calgarian be entitled to lay "breach of trust" charges and “discrimination” complaints.

Hats off to the honorable Dr. Dickson and the many of you here who felt obligated to protect people’s rights!

SAFE WATER CALGARY RESPONSE TO AMERICAN FLUORIDATION SOCIETY CLAIMS

It has come to our attention that the American Fluoridation Society (AFS) has written a response to Safe Water Calgary's critique of the CADTH report on artificial water fluoridation (https://docs.wixstatic.com/ugd/1eaedc_33811f3e342648da9164b619ff07d901.pdf).

Safe Water Calgary's (SWC) comments and corrections are below. There are far too many AFS misstatements to address individually and we wanted to keep this to a reasonable length. However, we felt it necessary to point out some major ones that are representative of virtually all of AFS's claims.

Some Untrue Statements

AFS (p. 2): **"To state that the Food and Drug Administration does not approve for fluoride to be added to water in the U.S., as the authors do, is absolutely false."**
SWC: *Our CADTH review never made this statement about the FDA*. We have no idea where it came from.

AFS (p. 3): **"Neither France, Germany, Belgium, nor the Netherlands has banned fluoridation, as is falsely claimed by the authors . . . statements cited by the authors . . . are simply unsubstantiated opinions solicited by FAN from individuals in those countries."**
SWC: Those "unsubstantiated opinions" are statements by high-level government officials (https://fluoridealert.org/content/europe-statements/):
France: Letter from L. Sanchez, Director de la Protection de l'Environement: **"Chemicals for drinking water treatment are listed in the State memorandum . . . Fluoride chemicals are not included. This is due to ethical as well as medical considerations."**
Germany: Letter from Gerda Hankel-Khan, Federal Ministry of Health: **"Generally, in Germany fluoridation of drinking water is forbidden."** She also cited **"the problematic nature of compulsion medication."**
Belgium: Letter from Chr. Legros, Director, Belgaqua: **"This water treatment has never been of use in Belgium and will never be (We hope so) into the future . . . The main reason for that is the fundamental position of the drinking water sector that it is not its task to deliver medicinal treatment to people. This is the sole responsibility of health services."**
Netherlands: Website statement from RIVM report 270091004/2007 for the Dutch Ministry of Health, Welfare and Sports: **"the addition of chemicals to drinking water is prohibited by law in the Netherlands. This law came into effect because it was widely perceived that drinking water should not be used as a vehicle for pharmaceuticals."**

AFS (p. 4): **"Water fluoridation is not the addition of a drug to water supplies."** And (p. 14): **"Fluoride in water supplies is not a drug."**
SWC (p. 5): According to Health Canada's definition of a drug, which AFS doesn't address, fluoride most assuredly is being used as a preventive drug. And it's instructive to see the above statements of some of the European nations banning fluoridation – they certainly consider fluoride in drinking water a drug too.

AFS (p. 6): **". . . contrary to the claim of the authors, the US EPA has not established there 'to be no safe levels of arsenic and lead.'"**
SWC: Yes, it has. These are the two EPA statements: **"There is no known safe level of lead in a child's blood"** https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water and **"The MCLG for arsenic is zero."** (https://safewater.zendesk.com/hc/en-us/articles/212077897-4-What-are-EPA-s-drinking-water-regulations-for-arsenic-) AFS is citing the maximum contaminant level (MCL) of arsenic and lead. MCL's are established by feasibility, which considers the cost of removing contaminants. AFS is either unaware or

conflating MCL's with the maximum contaminant level goal (MCLG), the level of a contaminant below which there is no known or expected risk to human health.

AFS (p. 10): **"Water fluoridation is not technically feasible"** (in Mexico, cited as a reason fluoridated salt is used).
SWC: There is no documentation whatsoever that fluoridation isn't technically feasible in Mexican cities or is the reason that Mexico offers salt (a consumer choice) instead of fluoridation. AFS has no citation to back up this statement.

AFS (p. 10): AFS asserted that the 2017 Bashash IQ study didn't adequately address numerous confounding factors, including family, education, maternal age, gestational age, birth weight, lead and mercury.
SWC: No, Bashash addressed and adjusted for each of these potential confounders. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915186/)

AFS (p. 12): "The Malin 2018 study was of the effects of iodine deficiency on the thyroid, not of fluoride on the thyroid."
SWC (p. 11): No, lead author Ashley Malin says just the opposite: **"I have grave concerns about the health effects of fluoride exposure . . . And not just from my study but the other studies that have come out in recent years."** (https://www.ehn.org/we-add-it-to-drinking-water-for-our-teeth-but-is-fluoride-hurting-us-2611193177.html?rebelltitem=1#rebelltitem1)

AFS (p. 15): **"There was no mention of concern with adverse effects on the immune system in the final (NRC) recommendation."**
SWC (p. 16): No, this is the definitive statement from the NRC report, p. 295: **"There is no question that fluoride can affect the cells involved in providing immune responses."** (https://www.nap.edu/catalog/11571/fluoride-in-drinking-water-a-scientific-review-of-epas-standards)

AFS (p. 17): Quoting Steven Levy, a dentist with the Iowa Fluoride Study: **"But we (IFS authors) did not say that we *'found no relation between tooth decay and the amount of fluoride swallowed.'*"**
SWC: *Our CADTH review never made this statement about no relation*. We have no idea where Dr. Levy got this quote from.

AFS (p. 19): Referring to a study on cost effectiveness that CADTH omitted, **"Thiessen, et al. which includes the false premise that mild dental fluorosis requires treatment."**
SWC: No, Thiessen specifically said: **"For this analysis, we assume that each moderate or severe fluorosis tooth receives a porcelain veneer treatment."** Mild fluorosis wasn't included in requiring treatment. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4457131/)

One Major Example of Selective Omissions: The Neurotoxicity Studies

It's revealing that AFS never mentioned the abstract SWC included in its appendix (p. 27) on the Green et al study, linking higher fluoride levels in the urine of pregnant women in Canada to a reduction of 4.5 IQ points in their male children. Funded by NIH and published in the Journal of the American Medical Association Pediatrics, it is widely considered one of the most robust studies ever conducted, with both the study authors and independent reviewers observing that fluoride's toxicity is equal to lead. The study was so strong that the editor of JAMA Pediatrics said he wouldn't want his wife to drink fluoridated water if she was pregnant.(https://fluoridealert.org/articles/jamacriticsims/)

AFS's selective omission of quotes is equally revealing. It includes the quote from Choi (p. 9) expressing limitations (all human studies have limitations) of her 2012 Harvard meta-analysis that found higher levels of fluoride associated with lower IQs in children in 26 out of 27 studies. AFS didn't quote co-author Philippe Grandjean, one of the leading neurotoxicity scientists in the world, who said **"Fluoride seems to fit in with lead, mercury, and**

other poisons that cause chemical brain drain." (https://www.hsph.harvard.edu/news/features/fluoride-childrens-health-grandjean-choi/)

Another glaring example is AFS's critique of the Bashash 2017 study that also found higher fluoride levels in pregnant women linked to significantly lower IQs in their children. AFS said it had **"limited, if any, applicability"** to U.S. fluoridated water. Principal author Howard Hu sees it differently: **"This is a very rigorous epidemiology study. You just can't deny it. It's directly related to whether fluoride is a risk for the neurodevelopment of children. So, to say it has no relevance to the folks in the U.S. seems disingenuous."** (http://fluoridealert.org/news/researchers-urge-caution-over-study-linking-fluoride-exposure-in-pregnancy-to-lower-iqs-in-children-2/)

One Major Half-truth: The National Research Council's 2006 report, *Fluoride in Drinking Water*

AFS cited NRC seven times. Their basic position (p. 7) was that NRC's only charge was **"to evaluate the adequacy of the EPA primary and secondary MCL's (maximum contaminant level) for fluoride, 4.0 ppm (parts per million) and 2.0 ppm respectively, to protect against adverse effects. The final recommendation . . . was for the primary MCL to be lowered from 4.0 ppm. The sole reasons cited by the Committee for this recommendation were the risk of severe dental fluorosis, bone fracture and skeletal fluorosis . . . Nothing else."**

SWC: There was definitely something else. The other charge to NRC (p. 2 at https://www.nap.edu/catalog/11571/fluoride-in-drinking-water-a-scientific-review-of-epas-standards):
"The committee was also asked to identify data gaps and to make recommendations for future research . . . " And NRC identified numerous gaps in the research data – for cancer, neurotoxicity (especially lowered IQ), diabetes, kidney disease, pineal gland function and dental fluorosis. And as mentioned in SWC's report, they made several unequivocal assertions, including (SWC's p. 8) that fluoride was an endocrine disruptor **and "The chief endocrine effects of fluoride . . . include decreased thyroid function."**

Bottom line: NRC's 2006 findings of fluoride's definite health risks and need for more research directly contradicted the certainty of fluoridation supporters *since the 1950's* that it had been proven safe.

One Major Misrepresentation: Dental Fluorosis

AFS: **"Mild to very mild dental fluorosis, the level which may be associated with optimally fluoridated water . . . " (i. e. fluoridation *isn't* associated with moderate and severe fluorosis)** and **"Clearly, dental fluorosis is not an issue of concern in association with the minuscule amount of fluoride in optimally fluoridated water, even in conjunction with fluoride intake from all normal sources."** (p. 13)

SWC: It's impossible to take AFS's claims seriously when they make statements like this.

1. *Even CADTH acknowledged fluoridation's role in increasing ALL levels of fluorosis:*
   "There was a significantly higher risk of developing dental fluorosis in high fluoridated areas compared with in low fluoridated areas. The additional studies identified from the updated literature search also found that the prevalence of dental fluorosis and its severity increased with increased water fluoride levels." (p. 13)
2. AFS completely omits the physical and psychological harm that can be caused by moderate fluorosis, which can lead to expensive treatment. (p. 14)
3. Two more recent high-level U.S. NHANES studies found much higher prevalence and severity than those used in the 2006 NRC report that AFS cited. (p. 13)
4. Fluoride, regardless of the source, causes fluorosis in a dose-response relationship. The more fluoride ingested by children ages 0-8, the higher the prevalence and severity of fluorosis. AFS's assertions that fluoridated water contributes to mild fluorosis, but somehow stops contributing to moderate and severe levels, is biologically absurd.

CPS2019-0965
Attachment 3

CADTH

CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

Community Water Fluoridation Exposure: A Review of Neurological and Cognitive Effects

Service Line: Rapid Response Service
Version: 1.0
Publication Date: October 23, 2019
Report Length: 24 Pages

CADTH

Cite As: Community Water Fluoridation: A Review of Neurological and Cognitive Effects. Ottawa: CADTH; 2019 Oct. (CADTH rapid response report: summary with critical appraisal).

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to Requests@CADTH.ca

Abbreviations

CI	Confidence interval
CWF	Community water fluoridation
FSIQ	Full Scale IQ
HOME	Home Observation for Measurement of the Environment
HTA	Health technology assessment
IQ	Intelligence quotient
MA	Meta-analysis
MIREC	Maternal-Infant Research on Environment Chemicals
MUF	Maternal urine fluoride
NR	Not reported
PIQ	Performance IQ
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomized controlled trial
SD	Standard deviation
SR	Systematic review
VIQ	Verbal IQ

Context and Policy Issues

In Canada, community water fluoridation (CWF) is the process of monitoring and controlling fluoride levels (by adding or removing fluoride) in the public water supply to reach the optimal level of 0.7 part per million (ppm) and not to exceed the maximum concentration of 1.5 ppm, as recommended in the 2010 *Health Canada Guidelines for Drinking Water Quality*.[1] CWF has been identified as a cost-effective method of delivering fluoride to the population and reducing dental caries in children and adults.[2,3] The Centers for Disease Control and Prevention recognized CWF as one of 10 great public health achievements of the 20th century because of its contribution to the prevention of tooth decay and improvement in oral health over the past 70 years.[4] CWF is endorsed by over 90 national and international governments and health organizations around the world.[5,6]

Despite the endorsement of governments and health organizations, and a large body of empirical evidence on the preventive effect of CWF on dental caries, a number of municipalities across Canada have not implemented or have discontinued water fluoridation.[7] In 2017, 38.7% of the Canadian population were exposed to community water systems having recommended optimal fluoride levels to protect their teeth.[7] Different factors contributed to CWF cessation including concerns about the potential harmful side effects of water fluoride to human health, including fluorosis, skeletal fractures, cancer, reproduction and development, thyroid function, and children's intelligence quotient (IQ).[1]

Multiple studies have been published showing that exposure to higher levels of fluoride in drinking water may be associated with lower intelligence among children.[8-11] However, the generalizability of the findings from those studies to the Canadian context is unlikely given they were conducted in rural areas and areas of low socioeconomic status in countries, such as China, India, Iran, or Mexico, which also include other sources of fluoride such as fluoridated salts or naturally occurring water fluoride levels that are many folds higher than the current Canadian levels.[8-11] Multiple methodological limitations were identified in these studies including the lack of control for important confounding variables such as exposure to known neurotoxicants (e.g., lead, arsenic, or iodine), socioeconomic status, nutritional status, and parental education that could be related to fluoride exposure and also potentially affect children's IQ.[12] The CADTH CWF Review of Dental Caries and Other Health Outcomes reviewed studies from countries with comparable water fluoride levels and socioeconomic parameters, and found no evidence for an association between water fluoridation at recommended Canadian levels and IQ or cognitive function.[12] A study published by a group of researchers in Canada and the US after the CADTH HTA concluded that exposure to higher levels of fluoride during pregnancy is associated with lower IQ scores in children aged 3 to 4 years in Canada.[13] The findings of that study prompted a further review on this topic.
The aim of this report is to review recent evidence on the effects of fluoride exposure through CWF at levels that are relevant to the Canadian context on the neurological or cognitive development in children and adolescents less than 18 years of age.

In this report, gender-neutral language has been used where possible in order to be inclusive of all gender identities. When reporting results from the published manuscript, gender-neutral language was not used in order to be consistent with the terms used in the source material.

Research Question

What are the neurological or cognitive effects of community water fluoridation, compared with non-fluoridated or different fluoride levels in drinking water, in individuals less than 18 years of age?

Key Findings

This review identified one prospective birth cohort study[13] examining the association between fluoride exposure of mothers during pregnancy and subsequent children's intelligence quotient scores at age 3 to 4 years. Both unadjusted and adjusted estimates showed no significant association between an increase of 1 mg/L in mother urine fluoride and Full Scale intelligence quotient score in the total sample of boys and girls, or in girls. Adjusted estimates also showed no statistically significant association between an increase of 1 mg/L in mother urine fluoride and performance intelligence quotient or verbal intelligence quotient in all children. In boys, every 1 mg/L increased in mothers' urine fluoride levels was associated with a 4.49 point lower intelligence quotient score. Every 1 mg increase in daily fluoride intake of mothers corresponded with 3.66 points lower in total children's intelligence quotient score. The interaction between child sex and maternal fluoride intake was not statistically significant. The evidence is weak due to multiple limitations (e.g., non-homogeneous distribution of data, potential errors and biases in the estimation of maternal fluoride exposure and in IQ measurement, uncontrolled potential important confounding factors); therefore, the findings of this study should be interpreted with caution.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were water fluorination and children (<18 years). No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2017 and September 13, 2019. The search dates were selected to identify information published subsequent to a previous search for the CADTH CWF Review of Dental Caries and Other Health Outcomes.[12]

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Persons less than 18 years of age (including *in utero*)
Intervention	Natural or artificial water fluoridation (range between 0.4 ppm to 1.5 ppm with the optimal level being 0.7 ppm)
Comparator	No water fluoridation, low fluoride level (< 0.4 ppm), or different fluoride levels in drinking water
Outcomes	Neurological (e.g., neurotoxicity) or cognitive outcomes (e.g., Intelligence Quotient)
Study Designs	Health technology assessments (HTAs), systematic reviews (SRs), randomized controlled trials (RCTs), and non-randomized studies

Exclusion Criteria

Studies were excluded if they did not meet the selection criteria in Table 1 and if they were published prior to 2017. Primary studies were also excluded if they had been included in the recent CADTH HTA report on CWF.[12]

Critical Appraisal of Individual Studies

The methodological quality (i.e., internal and external validity) of the included non-randomized study was assessed using the National Institute for Health and Care Excellence (NICE) checklist.[14] Summary scores were not calculated for the included study; rather, a review of the strengths and weaknesses were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 302 citations were identified in the literature search. Following screening of titles and abstracts, 294 citations were excluded and eight potentially relevant reports from the electronic search were retrieved for full-text review. No potentially relevant publication was retrieved from the grey literature search. Of the eight potentially relevant articles, seven publications were excluded for various reasons, while one study met the inclusion criteria and was included in this report. **Appendix 1** presents the PRISMA flowchart[15] of the study selection.

Summary of Study Characteristics

The characteristics of the identified study (Table 2) are presented in Appendix 2.

Study Design

The identified study was a prospective, multicentre birth cohort study,[13] which acquired data and frozen urine samples from the Canadian Maternal-Infant Research on Environmental Chemicals (MIREC) program. Maternal urine fluoride (MUF) concentrations were measured in urine spot samples collected at each trimester of gestation and adjusted for specific gravity (MUF_{SG}). Information regarding pregnant persons' consumption of tap water and other beverages such as tea and coffee was obtained using a self-reported questionnaire. The water fluoride concentrations in the areas where persons resided during pregnancy were estimated based on the levels of fluoride in the municipal water reported by waste water treatment plants and persons' postal code. Daily fluoride intake was estimated based on a combination of the above measures. IQ of children was assessed once at ages of three to four years.

Country of Origin

The identified study[13] was conducted by authors in Canada and the US.

Population

The MIREC study recruited 2,001 pregnant persons within the first 14 weeks of pregnancy from 10 Canadian cities. A subset of mother-child pairs (n = 610) from six of 10 cities (Vancouver, Montreal, Kingston, Toronto, Hamilton, and Halifax) were recruited for the measurement of children's IQ. Of 610 children, 601 had complete IQ data. Of 601 mother-child pairs, 369 had complete exposure and covariate data and drink tap water or live in a water treatment zone and were thus included in an analysis of the association between MUF and children's IQ. Further, 400 mother-child pairs had complete data and drink tap water or live in a water treatment zone and were included in a second analysis of the association between daily fluoride intake and children's IQ. Thus, 39.5% and 34.4% of the initial sample (n = 610) were excluded from the first and second analyses, respectively, due to missing data or ineligible exposure.

The mean age of pregnant persons at the time of recruitment was 32.3 years, and mean age of children at IQ testing was 3.4 years. Fifty two percent of children were female. Other characteristics of mothers and children are shown in Table 2 of Appendix 2.

Interventions and Comparators Mean MUF_{SG} value of the total sample of pregnant persons was 0.51 mg/L. The mean MUF_{SG} values of non-fluoridated and fluoridated groups were 0.40 mg/L and 0.69 mg/L, respectively.

Mean daily fluoride intake value of the total sample of pregnant persons was 0.54 mg. The mean daily fluoride intake values of non-fluoridated and fluoridated groups were 0.30 mg and 0.93 mg, respectively.

The average community fluoride level of areas of total sample of pregnant persons was 0.31 ppm. The mean water fluoride levels in the non-fluoridated and fluoridated areas were 0.13 ppm and 0.59 ppm, respectively.

Outcomes

The primary outcome was full scale IQ (FSIQ), a measure of global intellectual functioning, assessed using the Wechsler Preschool and Primary Scale of Intelligence, Third Edition (WPPSI-III).[16] Verbal IQ (VIQ), a measure of verbal reasoning, and performance IQ (PIQ), a measure of non-verbal reasoning, spatial processing and visual-motor skills, were also assessed. The WPPSI-III contains 14 subtests and two age ranges (from 2 years and 6 months to 3 years and 11 months, and from 4 years and 0 months to 7 years and 3 months). For children in the first age range, FSIQ, VIQ and PIQ scores are obtained from four core subtests. Seven core subtests are for children in the second age range. An overall intelligence score between 90 to 109 with a standard deviation of 15 is considered as average.[16,17] The reliability coefficients for WPPSI-III composite scales range from 0.89 to 0.95[16,17] [Reliability coefficient values range from 0.00 (significant error – no reliability) to 1.00 (no error – perfect reliability), and are used to indicate the amount of error in the scores]. The associations between children's IQ and maternal fluoride exposure (e.g., MUF, daily fluoride intake, water fluoride level) were estimated using linear regression analyses.

Summary of Critical Appraisal

The assessment of the methodological quality of the identified study is presented in Table 3 of Appendix 3.

Strengths

The identified study[13] was conducted in Canada with a well described source population.

The study assessed maternal fluoride exposure using a combination of mother urine fluoride, daily fluoride intake, in areas with or without fluoridation.

The study used linear regression analyses with two main measures of fluoride exposure (i.e., maternal fluoride urine and daily fluoride intake) to estimate the association between maternal fluoride exposure and children's IQ. Test statistics and associated *P* values were reported for all analyses.

The study analyzed mother urine fluoride concentration using established methods that were previously published. Children's' IQ (i.e., full scale IQ, verbal IQ and performance IQ) was assessed using a well-established method (i.e., the Wechsler Preschool and Primary Scale of Intelligence, third Edition).

Weaknesses

The recruitment of participants was not defined. It was unclear how 6 of 10 cities (Vancouver, Montreal, Kingston, Toronto, Hamilton, and Halifax) were chosen. The authors stated that, due to budgetary restraints, those cities were chosen as most participants fell into the age range required. While there was minimal difference between the MIREC sample, the sample of persons included in the analyses and the sample of persons who had incomplete MUF data, the study did not describe the method of selection of participants from the eligible population. There was no report on the percentage of selected individuals who agreed to participate. Thus, there is a potential risk of bias in selection of participants into the study.

The study did not clearly pre-define the level of fluoride exposure that was considered as low or high at start of the study. As participants were not randomly assigned to level of fluoride exposure at the beginning of the study, mother-child pairs were sorted out based on maternal urine fluoride and fluoride intake after maternal fluoride exposure was determined by a combination of maternal urine fluoride, daily fluoride intake and community water fluoride concentrations. This approach, together with the knowledge of children's IQ, might have affected the classification of exposure status of the mothers. The study did not report the period of fluoride exposure. Some persons might have a lifetime exposure, while others might just have exposure during pregnancy. This strategy may result in classification of intervention bias.

The study tried to link fluoride exposure through drinking tap water and IQ in children. However, fluoride exposure may not specifically come solely from CWF, but rather from other sources, including food and toothpaste. Other sources of fluoride were not accounted and controlled in the analyses.

Although the study used appropriate statistical analyses (e.g., multiple linear regression) to control for some confounding variables, other potential important confounding factors during pregnancy and after birth, as well as those between birth and children's age of 3 or 4 when IQ was assessed, were not fully addressed. Some potential important confounders included parental IQ, father's education, socioeconomic status, duration of breast feeding, postnatal exposure to fluoride, postnatal diet and nutrition, and child's health status.[18,19] There is a potential risk of bias due to confounding.

The outcome measures (i.e. FSIQ, PIQ, and VIQ) could have been influenced by the knowledge of intervention received, or fluoride exposure, as the authors were aware of potential correlation and association between higher maternal fluoride exposure and lower children's' IQ from previous studies. Systematic errors might exist in the measurement IQ, MUF and daily fluoride intake. No information was provided regarding IQ measurement, such as the number of times the test was given per child (as a single measure may not capture all cognitive performance),[20] when and where the test took place (different environments and times may give different results),[18] whether the child was comfortable with the examiner before the test,[17] and whether the outcome assessors were blinded (risk of detection bias). For urine fluoride, although the authors corrected for variations in urine dilution (e.g., samples collected in early morning is more concentrated than those collected in later of the day) by adjusting MUF for specific gravity, the accurate measure of true values of MUF that correctly reflect maternal fluoride exposure remains questionable, given the short half life of fluoride (about 5 hours),[21] and only three urine samples, one at each trimester, during the entire pregnancy. The estimation of the maternal daily fluoride intake may inherit inaccuracies due to the fact that the self-reported questionnaire and the estimation/calculation methods of fluoride intake have not been validated. The estimation was subjected to recall bias as it was based on self-reported estimates of the amount of tap water and types of tea (e.g., black tea has more fluoride than green tea) consumed per day, whose data were collected on only two occasions, first and third trimesters, of pregnancy. The daily fluoride intake did not consider other sources of fluoride such as food or swallowing toothpaste after toothbrushing. The accuracy of the estimated fluoride intake levels is questionable given the discrepancies compared with MUF_{SG} values. For example, the difference in values were lower in the non-fluoridated groups (0.30 mg relative to 0.40 mg/L) and higher in the fluoridated groups (0.93 mg relative to 0.69 mg/L).[21] Given the interrelationship between maternal fluoride exposure and IQ in the estimation of the association, any incorrect assessment of fluoride intake, MUF or IQ could have a great impact on the direction of bias due to measurement of outcomes.

The outcome, exposure and covariate data were not available for all, or nearly all, participants. Over one third of initial sample were excluded due to missing data of MUF, water fluoride, and covariates. Of the 601 mother-child pairs, 369 pairs were used for urine fluoride association analysis and 400 pairs for fluoride intake association analysis. There was no information regarding the proportion of participants and reasons for missing data between exposure to higher fluoride level and lower fluoride level. There is a potential risk of bias due to missing data.

The study did not report R-squared values for the regression lines, and *P* values were reported instead, which are known to be misleading.[22] In the first analysis with MUF_{SG}, the *P* value for interaction in boys was 0.02, and the second analysis with daily fluoride intake, the *P* value was 0.04. No sample size calculation was performed. Thus, it is unclear if the study was sufficiently powered to detect a meaningful effect, and whether or not there was a strong association between maternal fluoride exposure and children's IQ.

In summary, multiple methodological weaknesses that potentially affect the internal validity of the study results limit the generalizability of the findings to all pregnant persons in Canada.

Summary of Findings

The main findings and conclusion of the identified study[13] are presented in Table 4 of Appendix 4.

What are the neurological or cognitive effects of community water fluoridation, compared with non-fluoridated or different fluoride levels in drinking water, in individuals less than 18 years of age?

Children's FSIQ

The mean FSIQ score of the total children sample was 107.16 ± 13.26. The mean FSIQ scores of non-fluoridated and fluoridated groups were 108.07 ± 13.31 and 108.21 ± 13.72, respectively.

Boys had mean FSIQ scores of 104.61 ± 14.09 in the total sample, 106.31 ± 13.60 in non-fluoridated group, and 104.78 ± 14.71 in fluoridated group.

Girls had FSIQ scores of 109.56 ± 11.96 in the total sample, 109.86 ± 12.83 in non-fluoridated group, and 111.47 ± 11.89 in fluoridated group.

Associations between MUF_{SG} and FSIQ in children

Both unadjusted and adjusted estimates showed no significant association between an increase of 1 mg/L MUF_{SG} and FSIQ in the total sample of boys and girls, or in girls. In boys, an increase of 1 mg/L MUF_{SG} was associated with a significant reduction of 4.49 FSIQ score (95% confidence interval [CI] -8.38 to -0.60) after adjusting for covariates (city, Home Observation for Measurement of the Environment [HOME] score, maternal education, race/ethnicity, and child sex interaction). Likewise, an increase of 0.33 mg/L MUF_{SG} (a value spanning the interquartile range between 25th to 75th percentiles) or an increase of 0.70 mg/L MUF_{SG} (a value spanning the 80th central range between 10th to 90th percentiles) was associated with a significant reduction of 1.48 (95% CI -2.76 to -0.19) or 3.14 (95% CI -5.86 to -0.42) FSIQ score in boys, respectively.

Sensitivity analyses

Adjusting for maternal blood concentrations of lead, mercury, perfluorooctanoic acid, arsenic, manganese, or maternal secondhand smoke exposure alone did not change the overall estimate for the association between MUF_{SG} and FSIQ in boys or girls. Excluding data from two boys with FSIQ lower than 60 or use of the adjusted MUF for creatinine in the models did not markedly change the regression coefficient in boys.

Associations between maternal daily fluoride intake and FSIQ in children

Both unadjusted and adjusted estimates showed a significant association between daily fluoride intake and FSIQ in the total sample of boys and girls. An increase of 1 mg fluoride intake was associated with a significant reduction of 3.66 FSIQ score (95% CI -7.16 to -0.15) after adjusting for covariates (city, HOME score, maternal education, race/ethnicity, child sex and parental secondhand smoke exposure). Likewise, an increase of 0.62 mg fluoride intake (a value spanning the interquartile range between 25th to 75th percentiles) or an increase of 1.04 mg fluoride intake (a value spanning the 80th central range between 10th to 90th percentiles) was associated with a significant reduction of 2.26 (95% CI -4.45 to -0.09) or 3.80 (95% CI -7.46 to -0.16) FSIQ score, respectively. A subgroup analysis was not performed here, as the authors stated that the interaction between child sex and maternal fluoride intake was not statistically significant.

Associations between community water fluoride concentration and FSIQ in children

A 1-ppm (or 1-mg/L) increase in fluoride concentration in the community water was associated with a significant reduction of 5.29 FSIQ score in the total sample after adjusting for covariates (city, HOME score, maternal education, race/ethnicity, child sex and parental secondhand smoke exposure). No subgroup analysis was conducted, or reported, by sex.

Associations between MUF_{SG} and PIQ in children

Adjusted estimates showed no significant association between an increase of 1 mg/L MUF_{SG} and PIQ in total sample of boys and girls, or in girls. In boys, an increase of 1 mg/L MUF_{SG} was associated with a significant reduction of 4.63 PIQ score.

Associations between maternal daily fluoride intake and PIQ in children

Adjusted estimates showed no significant association between an increase of 1 mg daily fluoride intake and PIQ in total sample of boys and girls. Subgroups analyses based on child sex was either not performed or reported.

Associations between community water fluoride concentration and PIQ in children

A 1-ppm (or 1-mg/L) increase in fluoride concentration in the community water was associated with a significant reduction of 13.79 PIQ score (95% CI -18.82 to -7.28) in total sample after adjusting for covariates (HOME score, maternal education, race/ethnicity, child sex and parental secondhand smoke exposure). The city covariate was excluded from the model because it was strongly multi-collinear with water fluoride concentration. No subgroup analysis was conducted, or reported, by sex.

Associations between MUF_{SG} and VIQ in children

The adjusted estimate showed no significant association between an increase of 1 mg/L MUF_{SG} and VIQ in the total sample, in boys, or in girls.

Associations between maternal daily fluoride intake and VIQ in children

The adjusted estimate showed no significant association between an increase of 1 mg daily fluoride intake and VIQ in the total sample. A subgroup analysis based on child sex was not performed or reported.

Associations between community water fluoride concentration and VIQ in children

The adjusted estimate showed no significant association between an increase of 1 ppm fluoride concentration in the community water and VIQ in the total sample. A subgroup analysis based on child sex was not performed or reported.

Limitations

The study by Green et al., 2019[13] concluded that "*maternal exposure to higher levels of fluoride during pregnancy was associated with lower IQ scores in children aged 3 to 4 years.*" (p. E1) This conclusion was not supported by the data. Between nonfluoridated and fluoridated maternal exposure (assessed by MUF_{SG} or daily fluoride intake), the difference in mean FSIQ in total children (108.07 ± 13.31 versus 108.21 ± 13.72) was minimal. The average FSIQ in boys in the non-fluoridated and fluoridated groups were 106.31 ± 13.60 and 104.78 ± 14.71, respectively, and in girls were 109.86 ± 12.83 and 111.47 ± 11.89, respectively. According to the WPPSI test scoring,[17] these numbers were considered as normal, as a score of 90 to 109 represents average intelligence. Given that these values were available during data collection period, it was unclear about the authors' rationale to further explore the associations between maternal fluoride exposure and children's IQ. Indeed, adjusted estimates with a limited set of covariates showed no statistically significant association between an increase of 1 mg/L in MUF_{SG} and FSIQ, PIQ or VIQ in all children. These were not discussed or considered when formulating the conclusion. The authors performed subgroups analysis based on child sex and found that an increase of 1 mg/L MUF_{SG} was significantly associated with a 4.49 point lower (95% CI -8.38 to -0.60) in FSIQ only in boys. In contrast, there was a non-significant increase in IQ scores in girls associated with increase maternal fluoride exposure. No pre-registered protocol was reported as available, and it is possible that the decision to conduct a subgroup analysis based on sex was made post hoc. As indicated by the authors, further investigation is needed examining differences in boys versus girls regarding their vulnerability to neurocognitive effects associated with fluoride exposure. Further, no rationale is provided to suggest why an increase in daily fluoride intake was significantly associated with lower FSIQ in total children, while no association was seen with MUF_{SG}. For the interaction with child sex, the effect on fluoride exposure was seen in analysis with MUF_{SG} but not in analysis with fluoride intake. These results were inconsistent.

The 1-mg/L increase in MUF_{SG} that was used to examine the association between fluoride exposure and childrens' IQ was far larger than the MUF_{SG} difference between fluoridated and nonfluoridated exposure in reality, which was 0.29 mg/L (difference between 0.69 mg/L and 0.40 mg/L), corresponding with a deficit of 1.53 points in FSIQ in boys (difference between 104.78 and 106.31). This was corroborated with the 1.48 point deficit in FSIQ in boys, corresponding to a MUF_{SG} difference spanning the 25th to 75th percentile range, which was 0.33 mg/L. Given that the reliability coefficients of WPPSI test range from 0.89 to 0.95,[17] the 1.5 points or even 4.5 points deficit is within the range of error (i.e., 5% to 11%).

The estimated level of IQ deficit in boys is likely to be reflected by non-homogeneous distribution of data as relative to fluoride intake, or biases due to uncontrolled confounders. Most of the FSIQ data were concentrated in the lower end of the MUF_{SG} concentrations, with few observations at the extreme level; therefore, an assumption for a linear correlation may not be appropriate. It appears that the effect was not observed at low MUF_{SG} concentrations, and the overall association may be driven by some outliers and few points at the extreme MUF_{SG} concentrations. There were some boys in the sample with extremely low IQ with at least two with FSIQ scores in the 50s and five with FSIQ scores below 75, while all the girls' data points were above 80, as shown in Figure 3 of the study report.[13] Although the authors stated that a sensitivity analysis removing two boys with FSIQ scores in the 50s did not substantially change the overall estimate, data of boys below 75 were not taken into consideration in the sensitivity analysis. No attempt was made to control for potential important confounding factors including parental IQ, father's education, socioeconomic status, duration of breast feeding, postnatal exposure to fluoride, postnatal diet and nutrition, child's health status, and other confounders between birth and the children's age of 3 or 4 when IQ was measured.[18,19] Although the authors controlled for and performed sensitivity analysis to test the robustness of association estimates for a number of substances (including lead, mercury, arsenic) in the mothers' blood samples, they did not consider postnatal exposure of children to these substances. Lead, in particular has been found to have a high association with IQ in children.[23] With incomplete control for potential confounders, it remains uncertain to know if the effect is true, and if it is due to prenatal exposure or postnatal exposure.

Conclusions and Implications for Decision or Policy Making

This review identified one prospective birth cohort study[13] examining the association between fluoride exposure of mothers during pregnancy and subsequent children's IQ scores at age 3 to 4 years. Both unadjusted and adjusted estimates showed no significant association between an increase of 1 mg/L in MUF_{SG} and FSIQ in the total sample of boys and girls, or in girls. Adjusted estimates also showed no statistically significant association between an increase of 1 mg/L in MUF_{SG} and PIQ or VIQ in all children. In boys, every 1 mg/L increased in mothers' urine fluoride levels was associated with 4.49 points lower in FSIQ score. Every 1 mg increase in daily fluoride intake of mothers corresponded with 3.66 points lower in total children's FSIQ score. The interaction between child sex and maternal fluoride intake was not statistically significant. Given multiple aforementioned limitations (e.g., non-homogeneous distribution of data, potential errors and biases in the estimation of maternal fluoride exposure and in IQ measurement, uncontrolled potential important confounding factors), the findings of this study should be interpreted carefully.

A recent CADTH Review of Dental Caries and Other Health Outcomes report on CWF[12] found that water fluoridation levels relevant to the Canadian context is associated with reducing dental caries in children and adults, and there was no evidence that water fluoridation is associated with adverse effects on human health outcomes including cancer, hip fracture, Down syndrome, and IQ and cognitive function. For the IQ and cognitive function, the HTA report[12] identified three studies that were relevant to the Canadian context (a prospective cohort study in New Zealand,[24] an ecological study in Sweden,[25] and a cross-sectional study in Canada).[26] The New Zealand study[24] assessed IQ among participants at age 7 to 13 years, and subsequently at age 38 years, who were residents in areas with CWF (0.7 ppm to 1.0 ppm) and areas without CWF (≤ 0.3 ppm). The study found no clear differences in IQ between fluoridated and non-fluoridated groups and concluded that CWF programs at 0.7 ppm to 1.0 ppm is not neurotoxic. The Swedish study[25] investigated the effect of fluoride exposure through the drinking water throughout life on cognitive and non-cognitive ability, as well as math test scores in participants up to age 18 years. Fluoride in the community water supply in Sweden is naturally occurring and its level is kept at or below 1.5 ppm. The study found that water fluoride levels in Swedish drinking water had no effects on cognitive ability, non-cognitive ability, and math test scores. The Canadian study[26] examined the relationship between fluoride exposure (estimated from urine fluoride levels and tap water samples) and reported diagnosis of learning disability among children aged 3 to 12 years. The study found no association between fluoride exposure and reported learning disability (i.e., attention deficit disorder and attention deficit hyperactivity disorder) diagnosis among Canadian children.

The findings reported by the identified study[13] in this review provided weak evidence and should be interpreted carefully, given the multiple aforementioned limitations. This, along with other evidence described in the CADTH Review of Dental Caries and Other Health Outcomes on CWF[12] which demonstrated no association with IQ and cognitive function should be considered. The identified study should be viewed as part of the research effort to investigate possible associations between fluoride exposure and neurological development in children. Together with a larger body of evidence on this topic, further well conducted research is needed to reduce uncertainty.

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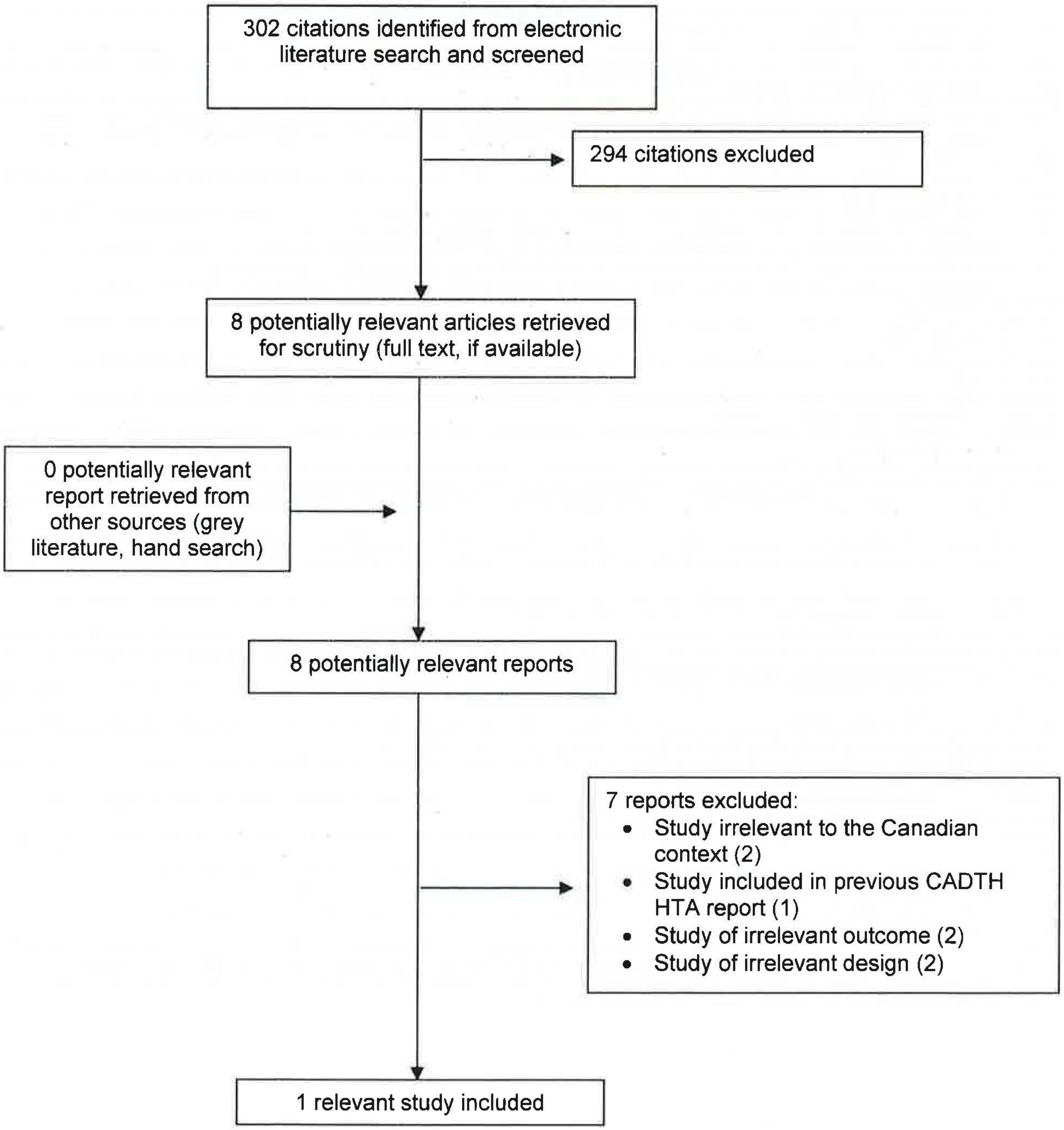
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Studies

Table 2: Characteristics of Included Primary Study

First Author, Publication Year, Country, Funding	Study Design and Analysis	Patient Characteristics	Interventions	Comparators	Outcomes
Green et al., 2019[13] Canada Funding: Public	Prospective birth cohort study Multicentre Sample size calculation: No Cohort was from the MIREC program that recruited 2,001 pregnant women from 10 cities across Canada A subset of 610 mother-child pairs from 6 out of 10 cities of the MIREC study was selected for neurodevelopment testing of children at ages 3 to 4 years	Mothers: Pregnant women within the first 14 weeks of pregnancy Mean age (SD): 32.33 (5.07) years White: 90 % Married or common law: 97% Bachelor's degree or higher: 68% Employed at time of pregnancy: 88% Net income household > $70,000 CAD: 71%	Exposure to higher levels of fluoride determined by MUF or fluoride intake, and correlated with living area having CWF	Exposure to lower levels of fluoride determined by MUF or fluoride intake, and correlated with living areas having non-CWF	Primary outcome: – FSIQ (measuring global intellectual functioning) Other outcomes: – VIQ (measuring verbal reasoning and comprehension) – PIQ (measuring nonverbal reasoning, spatial processing, and visual-motor skills)

First Author, Publication Year, Country, Funding	Study Design and Analysis	Patient Characteristics	Interventions	Comparators	Outcomes
	Up to 241 mother-child pairs were excluded due to various reasons, leaving 369 mother-child with MUF, IQ, complete covariates and water fluoride data, and 400 mother-child pairs with fluoride intake, IQ, complete covariates and water fluoride data Two sets of measurements: By MUF By fluoride intake Statistical analysis: Multiple linear regression analyses	Smoked in trimester 1: 2% Secondhand smoke at home: 4% Alcohol consumption (drink/month): None: 83% < 1: 8% ≥ 1: 9 Parity (first birth): 46% Children: Female: 52% Mean age (SD) at testing: 3.42 (0.32) years Mean gestation (SD): 39.12 (1.57) weeks Mean birth weight (SD): 3.47 (0.49) kg	Maternal fluoride exposure[a] measurements: Mean MUF_{SG} (SD) – Total sample: 0.51 (0.36) mg/L – Non-fluoridated areas: 0.40 (0.27) mg/L – Fluoridated areas: 0.69 (0.42) mg/L Mean daily fluoride intake (SD) – Total sample: 0.54 (0.44) mg – Non-fluoridated areas: 0.30 (0.26) mg – Fluoridated areas: 0.93 (0.43) mg Mean water fluoride level (SD) – Total sample: 0.31 (0.23) ppm – Non-fluoridated areas: 0.13 (0.06) ppm – Fluoridated areas: 0.59 (0.08) ppm		

CWF = community water fluoridation; FSIQ = Full Scale IQ; IQ = intelligence quotient; MIREC = Maternal-Infant Research on Environment Chemicals; MUF = maternal urine fluoride; PIQ = performance IQ; VIQ = verbal IQ

[a] Fluoride came from any source, not specifically from CWF

Appendix 3: Quality Assessment of Included Study

Table 3: Quality Assessment of Included Prospective Cohort Study

NICE Checklist[14]	Green et al., 2019[13]	
Question	**Answer**	**Comment**
SECTION 1: POPULATION		
1.1 Is the source population or source area well described?	Yes	The Maternal-Infant Research on Environment Chemicals (MIREC) recruited pregnant persons within the first 14 weeks of pregnancy from 10 cities in Canada. A subset of 610 mother-child pairs in the MIREC study were recruited from 6 of 10 cities: Vancouver, Montreal, Kingston, Toronto, Hamilton, and Halifax. Children aged 3 to 4 years.
1.2 Is the eligible population or area representative of the source population or area?	Probably no	The recruitment of individuals, clusters or areas was not defined. It was unclear how 6 of 10 cities were chosen.
1.3 Do the selected participants or areas represent the eligible population or area?	Probably no	The method of selection of participants from the eligible population was not described. There was no report on the percentage of selected individuals or clusters who agreed to participate. Risk of selection bias.
SECTION 2: METHOD OF ALLOCATION TO INTERVENTION (OR COMPARISON)		
2.1 Selection of exposure (and comparison) group. How was selection bias minimized?	Acceptable	Fluoride exposure assessed by areas of fluoridation or non-fluoridation, and by mother urine fluoride and daily fluoride intake. There was no clear pre-defined level of fluoride exposure that was considered as low or high at start of the study. Mother-child pairs were sorted out based on maternal urine fluoride and fluoride intake after mother had been exposed to fluoride, and the knowledge of children's IQ might have affected the classification of exposure status of the mothers.
2.2 Was the selection of explanatory variables based on sound theoretical basis	Probably no	Evidence for the hypothesis that maternal fluoride exposure was associated with lower IQ in children was drawn from studies conducted in countries not applicable to the Canadian context (e.g., use of fluoridated salts, or water fluoride levels many folds higher

NICE Checklist[14]	Green et al., 2019[13]	
		than the current recommended level in Canada)
2.3 Was the contamination acceptable low?	No	Fluoride exposure did not specifically come from CWF; it could be from other sources such as foods or swallowing toothpaste after toothbrushing.
2.4 How well were likely confounding factors identified and controlled?	Partially	Some confounding factors such as city, HOME score, maternal education, race/ethnicity, child sex, and prenatal secondhand smoke exposure were adjusted in the regression analysis.
2.5 Is the setting applicable to the Canadian context?	Yes	The study was conducted in Canada
SECTION 3: OUTCOMES		
3.1 Were the outcome measures and procedures reliable?	Partially	Mother urine fluoride concentration was analyzed using biochemical method previously published. Childrens' IQ was assessed using the Wechsler Preschool and Primary Scale of Intelligence, third Edition. The questionnaire used to collect the information on consumption of tap water and other beverages (tea, coffee) and the methods to estimate and calculate fluoride intake were not validated. Self-reported of dietary intake tends to be an unreliable measure.
3.2 Were the outcome measurements complete?	No	Results form all recruited participants were not reported. Over one third were excluded due to missing data. Unclear if missing IQ data from excluded children could affect the findings.
3.3 Were all the important outcomes assessed?	Yes	Full Scale IQ, verbal IQ and performance IQ were measured.
3.4 Was there a similar follow-up time in exposure and comparison groups?	Probably not	Unclear about the period of fluoride exposure of women. Some women might have a lifetime exposure, while others might just have exposure during pregnancy.
3.5 Was follow-up time meaningful?	Yes	All included children had lived in the areas since birth.
SECTION 4: ANALYSES		
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	Not reported	The study did not perform any sample calculation to obtain sufficient power to detect an intervention effect.
4.2 Were multiple explanatory variables considered in the analyses?	Yes	Two measures of fluoride exposure (maternal fluoride urine and fluoride intake) were used in the analyses for the association between fluoride exposure and children's IQ.

NICE Checklist[14]	Green et al., 2019[13]	
4.3 Were the analytical methods appropriate?	Probably Yes	Linear regression analyses were adjusted with some confounding factors. Multiple analyses of the intervention-outcome relationship (both unadjusted and adjusted data) were reported.
4.4 Was the precision of association given or calculable? Is association meaningful?	Probably yes	Test statistics and associated *P* values reported for all analyses. R-squared values for linear regression were not reported. Unclear if association was meaningful.
SECTION 5: SUMMARY		
5.1 Are the study results internally valid (i.e., unbiased)?	No	High risk of bias due to selection of participants, classification of intervention, confounding, missing data, and measurement of outcomes
5.2 Are the findings generalizable to the source population (i.e., externally valid)?	Probably not	Although the study was conducted in Canada, there was a risk of selection bias of the participants into the sample. The findings could not be generalizable to the entire Canadian population.

CWF = community water fluoridation; HOME = Home Observation for Measurement of the Environment; IQ = intelligence quotient

Appendix 4: Main Study Findings and Author's Conclusions

Table 4: Summary of Findings of Included Primary Study

Main Study Findings	Author's Conclusions
Green et al., 2019[13]	
Children's intellectual ability measurements[a] Mean FSIQ (SD) – Total sample: 107.16 (13.26) Boys: 104.61 (14.09) Girls: 109.56 (11.96) – Non-fluoridated areas: 108.07 (13.31) Boys: 106.31 (13.60) Girls: 109.86 (12.83) – Fluoridated areas: 108.21 (13.72) Boys: 104.78 (14.71) Girls: 111.47 (11.89) **Associations between fluoride exposure variables (MUF_{SG}, daily fluoride intake, or water fluoride concentration) and FSIQ** <u>Measurements with MUF_{SG}</u> Unadjusted estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 mg/L MUF_{SG} – Total sample: -2.60 (-5.80 to 0.60) Boys: -5.01 (-9.06 to -0.97) Girls: 2.23 (-2.77 to 7.23) Adjusted[b] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 mg/L MUF_{SG} – Total sample: -1.95 (-5.19 to 1.28) Boys: -4.49 (-8.38 to -0.60) Girls: 2.40 (-2.53 to 7.33) Adjusted[b] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 0.33 mg/L MUF_{SG} (a value spanning the interquartile range between 25th to 75th percentiles) – Total sample: -0.64 (-1.69 to 0.42) Boys: -1.48 (-2.76 to -0.19) Girls: 0.79 (-0.83 to 2.42) Adjusted[b] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 0.70 mg/L MUF_{SG} (a value spanning 80th central range between 10th to 90th percentiles) – Total sample: -1.36 (-3.58 to 0.90) Boys: -3.14 (-5.86 to -0.42) Girls: 1.68 (-1.77 to 5.13) <u>*Measurements with daily Fluoride Intake*</u> Unadjusted estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 mg of daily fluoride intake – Total sample: -3.19 (-5.94 to -0.44) Adjusted[c] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 mg of daily fluoride intake – Total sample: -3.66 (-7.16 to -0.15)	*"In this study, maternal exposure to higher levels of fluoride during pregnancy was associated with lower IQ scores in children aged 3 to 4 years. These findings indicate the possible need to reduce fluoride intake during pregnancy."[13]* p. E1

Main Study Findings	Author's Conclusions
Adjusted[c] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 0.62 mg of daily fluoride intake (a value spanning the interquartile range between 25th to 75th percentiles) – Total sample: -2.26 (-4.45 to -0.09) Adjusted[c] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1.04 mg of daily fluoride intake (a value spanning 80th central range between 10th to 90th percentiles) – Total sample: -3.80 (-7.46 to -0.16) *Measurements with water fluoride concentration* Unadjusted estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 ppm (or 1 mg/L) of water fluoride concentration – Total sample: 3.49 (-9.04 to 2.06) Adjusted[c] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 ppm (or 1 mg/L) of water fluoride concentration – Total sample: -5.29 (-10.39 to -0.19) **Sensitivity analyses predicting the associations between an increased of 1 mg/L of MUF_{SG} and FSIQ in boys, regression coefficients *B* (95% CI)** – Model A[d]: -4.49 (-8. 8.38 to -0.60) – Model A adjusting for lead: -4.61 (-8.50 to -0.71) – Model A adjusting for mercury: -5.13 (-9.16 to -1.10) – Model A adjusting for perfluorooctanoic acid: -4.57 (-8.21 to -0.50) – Model A adjusting for arsenic: -4.44 (-8.35 to -0.54) – Model A adjusting for manganese: -4.55 (-8.42 to -0.69) – Model A adjusting for secondhand smoke exposure: -4.18 (-8.06 to -0.30) – Model A excluding two boys with FSIQ lower than 60: -4.11 (-7.89 to -0.33) – Model A adjusting for creatinine: -6.96 (-8.56 to -1.36) **Associations between fluoride exposure variables (MUF_{SG}, daily fluoride intake, or water fluoride concentration) and PIQ** *Measurements with MUF_{SG}* Unadjusted estimates, regression coefficient *B* (95% CI) of PIQ for an increase of 1 mg/L MUF_{SG} – Total sample: -5.81 (-9.31 to -2.30) Boys: -8.11 (-13.29 to -4.32) Girls: -0.56 (-6.09 to 4.97) Adjusted[b] estimates, regression coefficient *B* (95% CI) of PIQ for an increase of 1 mg/L MUF_{SG} – Total sample: -1.24 (-4.88 to 2.40) Boys: -4.63 (-9.01 to -0.25) Girls: 4.50 (-1.02 to 10.05) *Measurements with daily Fluoride Intake* Unadjusted estimates, regression coefficient *B* (95% CI) of PIQ for an increase of 1 mg daily fluoride intake – Total sample: -5.75 (-8.74 to -2.76) Adjusted[c] estimates, regression coefficient *B* (95% CI) of PIQ for an increase of 1 mg daily fluoride intake – Total sample: -2.74 (-6.82 to 1.34) *Measurements with water fluoride concentration*	

<table>
<tr><th>Main Study Findings</th><th>Author's Conclusions</th></tr>
<tr><td>Adjusted[c] estimates, regression coefficient B (95% CI) of PIQ for an increase of 1 ppm (or 1 mg/L) of water fluoride concentration
– Total sample: -13.79 (-18.82 to -7.28)

Associations between fluoride exposure variables (MUF_{SG}, daily fluoride intake, or water fluoride concentration) and VIQ

<u>Measurements with MUF_{SG}</u>

Unadjusted estimates, regression coefficient B (95% CI) of VIQ for an increase of 1 mg/L MUF_{SG}
– Total sample: 1.28 (-1.87 to 4.43)
Boys: -0.21 (-4.19 to 3.77)
Girls: 4.78 (-0.14 to 9.70)

Adjusted[b] estimates, regression coefficient B (95% CI) of VIQ for an increase of 1 mg/L MUF_{SG}
– Total sample: -1.60 (-4.74 to 1.55)
Boys: -2.82 (-6.62 to 0.98)
Girls: 0.50 (-4.32 to 5.33)

<u>Measurements with daily Fluoride Intake</u>

Unadjusted estimates, regression coefficient B (95% CI) of VIQ for an increase of 1 mg daily fluoride intake
– Total sample: -0.03 (-2.71 to 2.64)

Adjusted[c] estimates, regression coefficient B (95% CI) of VIQ for an increased of 1 mg daily fluoride intake
– Total sample: -3.08 (-6.40 to 0.25)

<u>Measurements with water fluoride concentration</u>

Adjusted[c] estimates, regression coefficient B (95% CI) of VIQ for an increased of 1 ppm (or 1 mg/L) of water fluoride concentration
– Total sample: 3.37 (-1.50 to 8.24)</td><td></td></tr>
</table>

CWF = community water fluoridation; FSIQ = full Scale IQ; HOME = Home Observation for Measurement of the Environment; IQ = intelligence quotient; MUF_{SG} = maternal urine fluoride concentration adjusted for specific gravity; ppm = part per million (or mg/L); PIQ = performance IQ; SD = standard deviation; VIQ = verbal IQ

[a] Children intellectual ability was assessed using the Wechsler Preschool and Primary Scale of Intelligence, 3rd edition (WPPSI-III)[16] The WPPSI-III contains 14 subtests and two age ranges (from 2 years and 6 months to 3 years and 11 months, and from 4 years and 0 months to 7 years and 3 months). For children in the first age range, FSIQ, VIQ and PIQ scores are obtained from four core subtests. Seven core subtests are for children in the second age range.

[b] Adjusted for city, HOME score, maternal education, race/ethnicity, and child sex interaction.

[c] adjusted for city, HOME score, maternal education, race/ethnicity, child sex interaction, and prenatal secondhand smoke exposure.

FLUORIDATION'S NEUROTOXICITY

There is **no question** that fluoride is neurotoxic, damaging the brain and central nervous system, as documented by hundreds of studies. Extensive scientific evidence, including studies at exposures caused by fluoridated water, shows it can harm children. ***It can NOT be declared safe.***

2006: The National Research Council published Fluoride in Drinking Water[1], the most authoritative review of fluoride's toxicity. It stated unequivocally that "***fluorides have the ability to interfere with the functions of the brain and the body***" and "***the chief endocrine effects of fluoride include decreased thyroid function***." Low thyroid function (hypothyroidism) is known to be linked to lowering IQs.

2012: A Harvard-funded meta-analysis[2] found that children ingesting higher levels of fluoride tested an average 7 IQ points lower in **26 out of 27 studies**. Most had higher fluoride concentrations than in U.S. water, but many had total exposures to fluoride no more than what millions of Americans receive.

> ***"Fluoride seems to fit in with lead, mercury, and other poisons that cause chemical brain drain."***
> **Philippe Grandjean, MD, PhD, Harvard study co-author, Danish National Board of Health consultant, co-editor of Environmental Health, author of over 500 scientific papers**

2017: A petition to EPA[3] to end fluoridation documented that fluoride caused neurotoxic harm in **57 out of 61 human studies (mainly lowered IQ), several at levels in fluoridated water, and 112 out of 115 animal studies**. EPA denied the petition, triggering a lawsuit. A federal judge denied the EPA's motion to dismiss the suit. The legality of fluoridation is scheduled to go on trial in federal court in February 2020.

2017: A National Institutes of Health (NIH) - funded study[4] in Mexico covering 13 years found that every one milligram per liter (1 mg/L) increase in fluoride in pregnant women's urine – approximately the difference caused by ingestion of fluoridated water[5] - was associated with a reduction of their children's IQ by an average 5-6 points. Leonardo Trasande, a leading physician unaffiliated with the study, said it "**raises serious concerns about fluoride supplementation in water**."[6]

2018: A Canadian study[7] found iodine-deficient adults (nearly 18% of the population) with higher fluoride levels had a greater risk of hypothyroidism. Author Ashley Malin said "**I have grave concerns about the health effects of fluoride exposure.**"[8]

2019: Another NIH – funded study[9] in the Journal of the American Medical Association Pediatrics found every 1 mg/L increase in Canadian pregnant women's urine was linked to a 4.5 decrease in IQ in their male children. The study was so strong that the editor of JAMA Pediatrics said "**I would not have my wife drink fluoridated water**"[10] if she was pregnant. The authors and independent reviewers both said the study showed fluoride is as toxic as lead in lowering intelligence.

FLUORIDEALERT.ORG
Fluoride Action Network

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2. Choi et al https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3491930/
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7. Malin et al https://www.ncbi.nlm.nih.gov/pubmed/?term=till+malin+fluoride+thyroid
8. Environmental Health News, Oct. 10, 2018, https://www.ehn.org/we-add-it-to-drinking-water-for-our-teeth-but-is-fluoride-hurting-us-2611193177.html
9. Green et al, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6704756/
10. Washington Post, https://www.washingtonpost.com/science/2019/08/19/study-raises-questions-about-fluoride-childrens-iq/

HYDROFLUOSILICIC ACID

AVOID CONTACT WITH SKIN, EYES, MOUTH & CLOTHING

AVOID BREATHING FUMES OR VAPOR

DANGER POISON

DO NOT TAKE INTERNALLY

WARNING

DIRECTIONS FOR WATER FLUORIDATION: Application of this product for water fluoridation is subject to approval of all interested state and local health authorities. Its use should conform to the American Water Works Association's "Statement of Recommended Policy and Procedure."

Exact dosage must not raise the total fluoride concentration in drinking water above 1.5 ppm. (U.S. Public Health Service maximum limit)

IF MATERIAL IS SPILLED OR RELEASED, NEUTRALIZE WITH LIME AND DISPOSE AS CALCIUM FLUOSILICIC WASTE

SPECIAL PROTECTION INFORMATION: RESPIRATORS APPROVED FOR FLUORINE, RUBBER GLOVES, CHEMICAL GOGGLES AND A PROTECTIVE APRON OR ACID RESISTANT CLOTHING SHOULD BE USED SPECIAL PRECAUTIONS SHOULD BE TAKEN IN HANDLING AND STORING MATERIAL: AVOID STORAGE IN GLASS CONTAINERS.

WHEN MATERIAL IS CONTACTED WITH FIRE, FLUORIDE GAS MAY BE RELEASED. OVEREXPOSURE TO MATERIAL MAY CAUSE CONSTRICTED BREATHING COUGHING, SKIN REDNESS, OR BURNING OF THE THROAT.

ANTIDOTE

SKIN: COPIOUS AMOUNTS OF WATER FOR 15 MINUTES.
INTERNAL: CONTACT PHYSICIAN
OTHER: CONSULT PHYSICIAN IN THE EVENT INGESTION HAS OCCURRED.
GIVE COPIOUS AND REPEATED AMOUNTS OF WATER OR A WEAK SOLUTION OF CALCIUM CHLORIDE

Dear Green supporter,

There is a good reason why the green party opposes artificial water fluoridation. Water fluoridation is the dumping of industrial waste into the public water system. Health Canada said for fifty years that water fluoridation was "safe and effective" and that they had hundreds of studies to prove it. However, they always refused to show the purported studies. An access to information initiative from Alberta forced health Canada to admit they did not have such studies. For the past 62 years, folks in Calgary have worked hard against fluoride pushers. Powerful forces are now at work trying to re-introduce fluorosilicic acid to our public water system. We will not be able to keep our beautiful mountain water clean without a fight. We need your help. Join Safe Water Calgary and the battle to keep our public water free of toxic industrial waste. Thanks. Included is a DVD. It is everything they don't want you to know in 56 minutes!

CADTH

CADTH RAPID RESPONSE REPORT: SUMMARY WITH CRITICAL APPRAISAL

Community Water Fluoridation Exposure: A Review of Neurological and Cognitive Effects

Service Line: Rapid Response Service
Version: 1.0
Publication Date: October 23, 2019
Report Length: 24 Pages

CADTH

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ISSN: 1922-8147 (online)

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to Requests@CADTH.ca

Abbreviations

CI	Confidence interval
CWF	Community water fluoridation
FSIQ	Full Scale IQ
HOME	Home Observation for Measurement of the Environment
HTA	Health technology assessment
IQ	Intelligence quotient
MA	Meta-analysis
MIREC	Maternal-Infant Research on Environment Chemicals
MUF	Maternal urine fluoride
NR	Not reported
PIQ	Performance IQ
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomized controlled trial
SD	Standard deviation
SR	Systematic review
VIQ	Verbal IQ

Context and Policy Issues

In Canada, community water fluoridation (CWF) is the process of monitoring and controlling fluoride levels (by adding or removing fluoride) in the public water supply to reach the optimal level of 0.7 part per million (ppm) and not to exceed the maximum concentration of 1.5 ppm, as recommended in the 2010 *Health Canada Guidelines for Drinking Water Quality.*[1] CWF has been identified as a cost-effective method of delivering fluoride to the population and reducing dental caries in children and adults.[2,3] The Centers for Disease Control and Prevention recognized CWF as one of 10 great public health achievements of the 20th century because of its contribution to the prevention of tooth decay and improvement in oral health over the past 70 years.[4] CWF is endorsed by over 90 national and international governments and health organizations around the world.[5,6]

Despite the endorsement of governments and health organizations, and a large body of empirical evidence on the preventive effect of CWF on dental caries, a number of municipalities across Canada have not implemented or have discontinued water fluoridation.[7] In 2017, 38.7% of the Canadian population were exposed to community water systems having recommended optimal fluoride levels to protect their teeth.[7] Different factors contributed to CWF cessation including concerns about the potential harmful side effects of water fluoride to human health, including fluorosis, skeletal fractures, cancer, reproduction and development, thyroid function, and children's intelligence quotient (IQ).[1]

Multiple studies have been published showing that exposure to higher levels of fluoride in drinking water may be associated with lower intelligence among children.[8-11] However, the generalizability of the findings from those studies to the Canadian context is unlikely given they were conducted in rural areas and areas of low socioeconomic status in countries, such as China, India, Iran, or Mexico, which also include other sources of fluoride such as fluoridated salts or naturally occurring water fluoride levels that are many folds higher than the current Canadian levels.[8-11] Multiple methodological limitations were identified in these studies including the lack of control for important confounding variables such as exposure to known neurotoxicants (e.g., lead, arsenic, or iodine), socioeconomic status, nutritional status, and parental education that could be related to fluoride exposure and also potentially affect children's IQ.[12] The CADTH CWF Review of Dental Caries and Other Health Outcomes reviewed studies from countries with comparable water fluoride levels and socioeconomic parameters, and found no evidence for an association between water fluoridation at recommended Canadian levels and IQ or cognitive function.[12] A study published by a group of researchers in Canada and the US after the CADTH HTA concluded that exposure to higher levels of fluoride during pregnancy is associated with lower IQ scores in children aged 3 to 4 years in Canada.[13] The findings of that study prompted a further review on this topic.
The aim of this report is to review recent evidence on the effects of fluoride exposure through CWF at levels that are relevant to the Canadian context on the neurological or cognitive development in children and adolescents less than 18 years of age.

In this report, gender-neutral language has been used where possible in order to be inclusive of all gender identities. When reporting results from the published manuscript, gender-neutral language was not used in order to be consistent with the terms used in the source material.

Research Question

What are the neurological or cognitive effects of community water fluoridation, compared with non-fluoridated or different fluoride levels in drinking water, in individuals less than 18 years of age?

Key Findings

This review identified one prospective birth cohort study[13] examining the association between fluoride exposure of mothers during pregnancy and subsequent children's intelligence quotient scores at age 3 to 4 years. Both unadjusted and adjusted estimates showed no significant association between an increase of 1 mg/L in mother urine fluoride and Full Scale intelligence quotient score in the total sample of boys and girls, or in girls. Adjusted estimates also showed no statistically significant association between an increase of 1 mg/L in mother urine fluoride and performance intelligence quotient or verbal intelligence quotient in all children. In boys, every 1 mg/L increased in mothers' urine fluoride levels was associated with a 4.49 point lower intelligence quotient score. Every 1 mg increase in daily fluoride intake of mothers corresponded with 3.66 points lower in total children's intelligence quotient score. The interaction between child sex and maternal fluoride intake was not statistically significant. The evidence is weak due to multiple limitations (e.g., non-homogeneous distribution of data, potential errors and biases in the estimation of maternal fluoride exposure and in IQ measurement, uncontrolled potential important confounding factors); therefore, the findings of this study should be interpreted with caution.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were water fluorination and children (<18 years). No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2017 and September 13, 2019. The search dates were selected to identify information published subsequent to a previous search for the CADTH CWF Review of Dental Caries and Other Health Outcomes.[12]

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Persons less than 18 years of age (including *in utero*)
Intervention	Natural or artificial water fluoridation (range between 0.4 ppm to 1.5 ppm with the optimal level being 0.7 ppm)
Comparator	No water fluoridation, low fluoride level (< 0.4 ppm), or different fluoride levels in drinking water
Outcomes	Neurological (e.g., neurotoxicity) or cognitive outcomes (e.g., Intelligence Quotient)
Study Designs	Health technology assessments (HTAs), systematic reviews (SRs), randomized controlled trials (RCTs), and non-randomized studies

Exclusion Criteria

Studies were excluded if they did not meet the selection criteria in Table 1 and if they were published prior to 2017. Primary studies were also excluded if they had been included in the recent CADTH HTA report on CWF.[12]

Critical Appraisal of Individual Studies

The methodological quality (i.e., internal and external validity) of the included non-randomized study was assessed using the National Institute for Health and Care Excellence (NICE) checklist.[14] Summary scores were not calculated for the included study; rather, a review of the strengths and weaknesses were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 302 citations were identified in the literature search. Following screening of titles and abstracts, 294 citations were excluded and eight potentially relevant reports from the electronic search were retrieved for full-text review. No potentially relevant publication was retrieved from the grey literature search. Of the eight potentially relevant articles, seven publications were excluded for various reasons, while one study met the inclusion criteria and was included in this report. **Appendix 1** presents the PRISMA flowchart[15] of the study selection.

Summary of Study Characteristics

The characteristics of the identified study (Table 2) are presented in Appendix 2.

Study Design

The identified study was a prospective, multicentre birth cohort study,[13] which acquired data and frozen urine samples from the Canadian Maternal-Infant Research on Environmental Chemicals (MIREC) program. Maternal urine fluoride (MUF) concentrations were measured in urine spot samples collected at each trimester of gestation and adjusted for specific gravity (MUF_{SG}). Information regarding pregnant persons' consumption of tap water and other beverages such as tea and coffee was obtained using a self-reported questionnaire. The water fluoride concentrations in the areas where persons resided during pregnancy were estimated based on the levels of fluoride in the municipal water reported by waste water treatment plants and persons' postal code. Daily fluoride intake was estimated based on a combination of the above measures. IQ of children was assessed once at ages of three to four years.

CADTH

Country of Origin

The identified study[13] was conducted by authors in Canada and the US.

Population

The MIREC study recruited 2,001 pregnant persons within the first 14 weeks of pregnancy from 10 Canadian cities. A subset of mother-child pairs (n = 610) from six of 10 cities (Vancouver, Montreal, Kingston, Toronto, Hamilton, and Halifax) were recruited for the measurement of children's IQ. Of 610 children, 601 had complete IQ data. Of 601 mother-child pairs, 369 had complete exposure and covariate data and drink tap water or live in a water treatment zone and were thus included in an analysis of the association between MUF and children's IQ. Further, 400 mother-child pairs had complete data and drink tap water or live in a water treatment zone and were included in a second analysis of the association between daily fluoride intake and children's IQ. Thus, 39.5% and 34.4% of the initial sample (n = 610) were excluded from the first and second analyses, respectively, due to missing data or ineligible exposure.

The mean age of pregnant persons at the time of recruitment was 32.3 years, and mean age of children at IQ testing was 3.4 years. Fifty two percent of children were female. Other characteristics of mothers and children are shown in Table 2 of Appendix 2.

Interventions and Comparators Mean MUF_{SG} value of the total sample of pregnant persons was 0.51 mg/L. The mean MUF_{SG} values of non-fluoridated and fluoridated groups were 0.40 mg/L and 0.69 mg/L, respectively.

Mean daily fluoride intake value of the total sample of pregnant persons was 0.54 mg. The mean daily fluoride intake values of non-fluoridated and fluoridated groups were 0.30 mg and 0.93 mg, respectively.

The average community fluoride level of areas of total sample of pregnant persons was 0.31 ppm. The mean water fluoride levels in the non-fluoridated and fluoridated areas were 0.13 ppm and 0.59 ppm, respectively.

Outcomes

The primary outcome was full scale IQ (FSIQ), a measure of global intellectual functioning, assessed using the Wechsler Preschool and Primary Scale of Intelligence, Third Edition (WPPSI-III).[16] Verbal IQ (VIQ), a measure of verbal reasoning, and performance IQ (PIQ), a measure of non-verbal reasoning, spatial processing and visual-motor skills, were also assessed. The WPPSI-III contains 14 subtests and two age ranges (from 2 years and 6 months to 3 years and 11 months, and from 4 years and 0 months to 7 years and 3 months). For children in the first age range, FSIQ, VIQ and PIQ scores are obtained from four core subtests. Seven core subtests are for children in the second age range. An overall intelligence score between 90 to 109 with a standard deviation of 15 is considered as average.[16,17] The reliability coefficients for WPPSI-III composite scales range from 0.89 to 0.95[16,17] [Reliability coefficient values range from 0.00 (significant error – no reliability) to 1.00 (no error – perfect reliability), and are used to indicate the amount of error in the scores]. The associations between children's IQ and maternal fluoride exposure (e.g., MUF, daily fluoride intake, water fluoride level) were estimated using linear regression analyses.

Summary of Critical Appraisal

The assessment of the methodological quality of the identified study is presented in Table 3 of Appendix 3.

Strengths

The identified study[13] was conducted in Canada with a well described source population.

The study assessed maternal fluoride exposure using a combination of mother urine fluoride, daily fluoride intake, in areas with or without fluoridation.

The study used linear regression analyses with two main measures of fluoride exposure (i.e., maternal fluoride urine and daily fluoride intake) to estimate the association between maternal fluoride exposure and children's IQ. Test statistics and associated *P* values were reported for all analyses.

The study analyzed mother urine fluoride concentration using established methods that were previously published. Children's' IQ (i.e., full scale IQ, verbal IQ and performance IQ) was assessed using a well-established method (i.e., the Wechsler Preschool and Primary Scale of Intelligence, third Edition).

Weaknesses

The recruitment of participants was not defined. It was unclear how 6 of 10 cities (Vancouver, Montreal, Kingston, Toronto, Hamilton, and Halifax) were chosen. The authors stated that, due to budgetary restraints, those cities were chosen as most participants fell into the age range required. While there was minimal difference between the MIREC sample, the sample of persons included in the analyses and the sample of persons who had incomplete MUF data, the study did not describe the method of selection of participants from the eligible population. There was no report on the percentage of selected individuals who agreed to participate. Thus, there is a potential risk of bias in selection of participants into the study.

The study did not clearly pre-define the level of fluoride exposure that was considered as low or high at start of the study. As participants were not randomly assigned to level of fluoride exposure at the beginning of the study, mother-child pairs were sorted out based on maternal urine fluoride and fluoride intake after maternal fluoride exposure was determined by a combination of maternal urine fluoride, daily fluoride intake and community water fluoride concentrations. This approach, together with the knowledge of children's IQ, might have affected the classification of exposure status of the mothers. The study did not report the period of fluoride exposure. Some persons might have a lifetime exposure, while others might just have exposure during pregnancy. This strategy may result in classification of intervention bias.

The study tried to link fluoride exposure through drinking tap water and IQ in children. However, fluoride exposure may not specifically come solely from CWF, but rather from other sources, including food and toothpaste. Other sources of fluoride were not accounted and controlled in the analyses.

Although the study used appropriate statistical analyses (e.g., multiple linear regression) to control for some confounding variables, other potential important confounding factors during pregnancy and after birth, as well as those between birth and children's age of 3 or 4 when IQ was assessed, were not fully addressed. Some potential important confounders included parental IQ, father's education, socioeconomic status, duration of breast feeding, postnatal exposure to fluoride, postnatal diet and nutrition, and child's health status.[18,19] There is a potential risk of bias due to confounding.

The outcome measures (i.e. FSIQ, PIQ, and VIQ) could have been influenced by the knowledge of intervention received, or fluoride exposure, as the authors were aware of potential correlation and association between higher maternal fluoride exposure and lower children's' IQ from previous studies. Systematic errors might exist in the measurement IQ, MUF and daily fluoride intake. No information was provided regarding IQ measurement, such as the number of times the test was given per child (as a single measure may not capture all cognitive performance),[20] when and where the test took place (different environments and times may give different results),[18] whether the child was comfortable with the examiner before the test,[17] and whether the outcome assessors were blinded (risk of detection bias). For urine fluoride, although the authors corrected for variations in urine dilution (e.g., samples collected in early morning is more concentrated than those collected in later of the day) by adjusting MUF for specific gravity, the accurate measure of true values of MUF that correctly reflect maternal fluoride exposure remains questionable, given the short half life of fluoride (about 5 hours),[21] and only three urine samples, one at each trimester, during the entire pregnancy. The estimation of the maternal daily fluoride intake may inherit inaccuracies due to the fact that the self-reported questionnaire and the estimation/calculation methods of fluoride intake have not been validated. The estimation was subjected to recall bias as it was based on self-reported estimates of the amount of tap water and types of tea (e.g., black tea has more fluoride than green tea) consumed per day, whose data were collected on only two occasions, first and third trimesters, of pregnancy. The daily fluoride intake did not consider other sources of fluoride such as food or swallowing toothpaste after toothbrushing. The accuracy of the estimated fluoride intake levels is questionable given the discrepancies compared with MUF_{SG} values. For example, the difference in values were lower in the non-fluoridated groups (0.30 mg relative to 0.40 mg/L) and higher in the fluoridated groups (0.93 mg relative to 0.69 mg/L).[21] Given the interrelationship between maternal fluoride exposure and IQ in the estimation of the association, any incorrect assessment of fluoride intake, MUF or IQ could have a great impact on the direction of bias due to measurement of outcomes.

The outcome, exposure and covariate data were not available for all, or nearly all, participants. Over one third of initial sample were excluded due to missing data of MUF, water fluoride, and covariates. Of the 601 mother-child pairs, 369 pairs were used for urine fluoride association analysis and 400 pairs for fluoride intake association analysis. There was no information regarding the proportion of participants and reasons for missing data between exposure to higher fluoride level and lower fluoride level. There is a potential risk of bias due to missing data.

The study did not report R-squared values for the regression lines, and *P* values were reported instead, which are known to be misleading.[22] In the first analysis with MUF_{SG}, the *P* value for interaction in boys was 0.02, and the second analysis with daily fluoride intake, the *P* value was 0.04. No sample size calculation was performed. Thus, it is unclear if the study was sufficiently powered to detect a meaningful effect, and whether or not there was a strong association between maternal fluoride exposure and children's IQ.

In summary, multiple methodological weaknesses that potentially affect the internal validity of the study results limit the generalizability of the findings to all pregnant persons in Canada.

Summary of Findings

The main findings and conclusion of the identified study[13] are presented in Table 4 of Appendix 4.

What are the neurological or cognitive effects of community water fluoridation, compared with non-fluoridated or different fluoride levels in drinking water, in individuals less than 18 years of age?

Children's FSIQ

The mean FSIQ score of the total children sample was 107.16 ± 13.26. The mean FSIQ scores of non-fluoridated and fluoridated groups were 108.07 ± 13.31 and 108.21 ± 13.72, respectively.

Boys had mean FSIQ scores of 104.61 ± 14.09 in the total sample, 106.31 ± 13.60 in non-fluoridated group, and 104.78 ± 14.71 in fluoridated group.

Girls had FSIQ scores of 109.56 ± 11.96 in the total sample, 109.86 ± 12.83 in non-fluoridated group, and 111.47 ± 11.89 in fluoridated group.

Associations between MUF_{SG} and FSIQ in children

Both unadjusted and adjusted estimates showed no significant association between an increase of 1 mg/L MUF_{SG} and FSIQ in the total sample of boys and girls, or in girls. In boys, an increase of 1 mg/L MUF_{SG} was associated with a significant reduction of 4.49 FSIQ score (95% confidence interval [CI] -8.38 to -0.60) after adjusting for covariates (city, Home Observation for Measurement of the Environment [HOME] score, maternal education, race/ethnicity, and child sex interaction). Likewise, an increase of 0.33 mg/L MUF_{SG} (a value spanning the interquartile range between 25th to 75th percentiles) or an increase of 0.70 mg/L MUF_{SG} (a value spanning the 80th central range between 10th to 90th percentiles) was associated with a significant reduction of 1.48 (95% CI -2.76 to -0.19) or 3.14 (95% CI -5.86 to -0.42) FSIQ score in boys, respectively.

Sensitivity analyses

Adjusting for maternal blood concentrations of lead, mercury, perfluorooctanoic acid, arsenic, manganese, or maternal secondhand smoke exposure alone did not change the overall estimate for the association between MUF_{SG} and FSIQ in boys or girls. Excluding data from two boys with FSIQ lower than 60 or use of the adjusted MUF for creatinine in the models did not markedly change the regression coefficient in boys.

Associations between maternal daily fluoride intake and FSIQ in children

Both unadjusted and adjusted estimates showed a significant association between daily fluoride intake and FSIQ in the total sample of boys and girls. An increase of 1 mg fluoride intake was associated with a significant reduction of 3.66 FSIQ score (95% CI -7.16 to -0.15) after adjusting for covariates (city, HOME score, maternal education, race/ethnicity, child sex and parental secondhand smoke exposure). Likewise, an increase of 0.62 mg fluoride intake (a value spanning the interquartile range between 25th to 75th percentiles) or an increase of 1.04 mg fluoride intake (a value spanning the 80th central range between 10th to 90th percentiles) was associated with a significant reduction of 2.26 (95% CI -4.45 to -0.09) or 3.80 (95% CI -7.46 to -0.16) FSIQ score, respectively. A subgroup analysis was not performed here, as the authors stated that the interaction between child sex and maternal fluoride intake was not statistically significant.

Associations between community water fluoride concentration and FSIQ in children

A 1-ppm (or 1-mg/L) increase in fluoride concentration in the community water was associated with a significant reduction of 5.29 FSIQ score in the total sample after adjusting for covariates (city, HOME score, maternal education, race/ethnicity, child sex and parental secondhand smoke exposure). No subgroup analysis was conducted, or reported, by sex.

Associations between MUF_{SG} and PIQ in children

Adjusted estimates showed no significant association between an increase of 1 mg/L MUF_{SG} and PIQ in total sample of boys and girls, or in girls. In boys, an increase of 1 mg/L MUF_{SG} was associated with a significant reduction of 4.63 PIQ score.

Associations between maternal daily fluoride intake and PIQ in children

Adjusted estimates showed no significant association between an increase of 1 mg daily fluoride intake and PIQ in total sample of boys and girls. Subgroups analyses based on child sex was either not performed or reported.

Associations between community water fluoride concentration and PIQ in children

A 1-ppm (or 1-mg/L) increase in fluoride concentration in the community water was associated with a significant reduction of 13.79 PIQ score (95% CI -18.82 to -7.28) in total sample after adjusting for covariates (HOME score, maternal education, race/ethnicity, child sex and parental secondhand smoke exposure). The city covariate was excluded from the model because it was strongly multi-collinear with water fluoride concentration. No subgroup analysis was conducted, or reported, by sex.

Associations between MUF_{SG} and VIQ in children

The adjusted estimate showed no significant association between an increase of 1 mg/L MUF_{SG} and VIQ in the total sample, in boys, or in girls.

Associations between maternal daily fluoride intake and VIQ in children

The adjusted estimate showed no significant association between an increase of 1 mg daily fluoride intake and VIQ in the total sample. A subgroup analysis based on child sex was not performed or reported.

Associations between community water fluoride concentration and VIQ in children

The adjusted estimate showed no significant association between an increase of 1 ppm fluoride concentration in the community water and VIQ in the total sample. A subgroup analysis based on child sex was not performed or reported.

Limitations

The study by Green et al., 2019[13] concluded that "*maternal exposure to higher levels of fluoride during pregnancy was associated with lower IQ scores in children aged 3 to 4 years.*" (p. E1) This conclusion was not supported by the data. Between nonfluoridated and fluoridated maternal exposure (assessed by MUF_{SG} or daily fluoride intake), the difference in mean FSIQ in total children (108.07 ± 13.31 versus 108.21 ± 13.72) was minimal. The average FSIQ in boys in the non-fluoridated and fluoridated groups were 106.31 ± 13.60 and 104.78 ± 14.71, respectively, and in girls were 109.86 ± 12.83 and 111.47 ± 11.89, respectively. According to the WPPSI test scoring,[17] these numbers were considered as normal, as a score of 90 to 109 represents average intelligence. Given that these values were available during data collection period, it was unclear about the authors' rationale to further explore the associations between maternal fluoride exposure and children's IQ. Indeed, adjusted estimates with a limited set of covariates showed no statistically significant association between an increase of 1 mg/L in MUF_{SG} and FSIQ, PIQ or VIQ in all children. These were not discussed or considered when formulating the conclusion. The authors performed subgroups analysis based on child sex and found that an increase of 1 mg/L MUF_{SG} was significantly associated with a 4.49 point lower (95% CI -8.38 to -0.60) in FSIQ only in boys. In contrast, there was a non-significant increase in IQ scores in girls associated with increase maternal fluoride exposure. No pre-registered protocol was reported as available, and it is possible that the decision to conduct a subgroup analysis based on sex was made post hoc. As indicated by the authors, further investigation is needed examining differences in boys versus girls regarding their vulnerability to neurocognitive effects associated with fluoride exposure. Further, no rationale is provided to suggest why an increase in daily fluoride intake was significantly associated with lower FSIQ in total children, while no association was seen with MUF_{SG}. For the interaction with child sex, the effect on fluoride exposure was seen in analysis with MUF_{SG} but not in analysis with fluoride intake. These results were inconsistent.

The 1-mg/L increase in MUF_{SG} that was used to examine the association between fluoride exposure and childrens' IQ was far larger than the MUF_{SG} difference between fluoridated and nonfluoridated exposure in reality, which was 0.29 mg/L (difference between 0.69 mg/L and 0.40 mg/L), corresponding with a deficit of 1.53 points in FSIQ in boys (difference between 104.78 and 106.31). This was corroborated with the 1.48 point deficit in FSIQ in boys, corresponding to a MUF_{SG} difference spanning the 25^{th} to 75^{th} percentile range, which was 0.33 mg/L. Given that the reliability coefficients of WPPSI test range from 0.89 to 0.95,[17] the 1.5 points or even 4.5 points deficit is within the range of error (i.e., 5% to 11%).

The estimated level of IQ deficit in boys is likely to be reflected by non-homogeneous distribution of data as relative to fluoride intake, or biases due to uncontrolled confounders. Most of the FSIQ data were concentrated in the lower end of the MUF_{SG} concentrations, with few observations at the extreme level; therefore, an assumption for a linear correlation may not be appropriate. It appears that the effect was not observed at low MUF_{SG} concentrations, and the overall association may be driven by some outliers and few points at the extreme MUF_{SG} concentrations. There were some boys in the sample with extremely low IQ with at least two with FSIQ scores in the 50s and five with FSIQ scores below 75, while all the girls' data points were above 80, as shown in Figure 3 of the study report.[13] Although the authors stated that a sensitivity analysis removing two boys with FSIQ scores in the 50s did not substantially change the overall estimate, data of boys below 75 were not taken into consideration in the sensitivity analysis. No attempt was made to control for potential important confounding factors including parental IQ, father's education, socioeconomic status, duration of breast feeding, postnatal exposure to fluoride, postnatal diet and nutrition, child's health status, and other confounders between birth and the children's age of 3 or 4 when IQ was measured.[18,19] Although the authors controlled for and performed sensitivity analysis to test the robustness of association estimates for a number of substances (including lead, mercury, arsenic) in the mothers' blood samples, they did not consider postnatal exposure of children to these substances. Lead, in particular has been found to have a high association with IQ in children.[23] With incomplete control for potential confounders, it remains uncertain to know if the effect is true, and if it is due to prenatal exposure or postnatal exposure.

Conclusions and Implications for Decision or Policy Making

This review identified one prospective birth cohort study[13] examining the association between fluoride exposure of mothers during pregnancy and subsequent children's IQ scores at age 3 to 4 years. Both unadjusted and adjusted estimates showed no significant association between an increase of 1 mg/L in MUF_{SG} and FSIQ in the total sample of boys and girls, or in girls. Adjusted estimates also showed no statistically significant association between an increase of 1 mg/L in MUF_{SG} and PIQ or VIQ in all children. In boys, every 1 mg/L increased in mothers' urine fluoride levels was associated with 4.49 points lower in FSIQ score. Every 1 mg increase in daily fluoride intake of mothers corresponded with 3.66 points lower in total children's FSIQ score. The interaction between child sex and maternal fluoride intake was not statistically significant. Given multiple aforementioned limitations (e.g., non-homogeneous distribution of data, potential errors and biases in the estimation of maternal fluoride exposure and in IQ measurement, uncontrolled potential important confounding factors), the findings of this study should be interpreted carefully.

A recent CADTH Review of Dental Caries and Other Health Outcomes report on CWF[12] found that water fluoridation levels relevant to the Canadian context is associated with reducing dental caries in children and adults, and there was no evidence that water fluoridation is associated with adverse effects on human health outcomes including cancer, hip fracture, Down syndrome, and IQ and cognitive function. For the IQ and cognitive function, the HTA report[12] identified three studies that were relevant to the Canadian context (a prospective cohort study in New Zealand,[24] an ecological study in Sweden,[25] and a cross-sectional study in Canada).[26] The New Zealand study[24] assessed IQ among participants at age 7 to 13 years, and subsequently at age 38 years, who were residents in areas with CWF (0.7 ppm to 1.0 ppm) and areas without CWF (≤ 0.3 ppm). The study found no clear differences in IQ between fluoridated and non-fluoridated groups and concluded that CWF programs at 0.7 ppm to 1.0 ppm is not neurotoxic. The Swedish study[25] investigated the effect of fluoride exposure through the drinking water throughout life on cognitive and non-cognitive ability, as well as math test scores in participants up to age 18 years. Fluoride in the community water supply in Sweden is naturally occurring and its level is kept at or below 1.5 ppm. The study found that water fluoride levels in Swedish drinking water had no effects on cognitive ability, non-cognitive ability, and math test scores. The Canadian study[26] examined the relationship between fluoride exposure (estimated from urine fluoride levels and tap water samples) and reported diagnosis of learning disability among children aged 3 to 12 years. The study found no association between fluoride exposure and reported learning disability (i.e., attention deficit disorder and attention deficit hyperactivity disorder) diagnosis among Canadian children.

The findings reported by the identified study[13] in this review provided weak evidence and should be interpreted carefully, given the multiple aforementioned limitations. This, along with other evidence described in the CADTH Review of Dental Caries and Other Health Outcomes on CWF[12] which demonstrated no association with IQ and cognitive function should be considered. The identified study should be viewed as part of the research effort to investigate possible associations between fluoride exposure and neurological development in children. Together with a larger body of evidence on this topic, further well conducted research is needed to reduce uncertainty.

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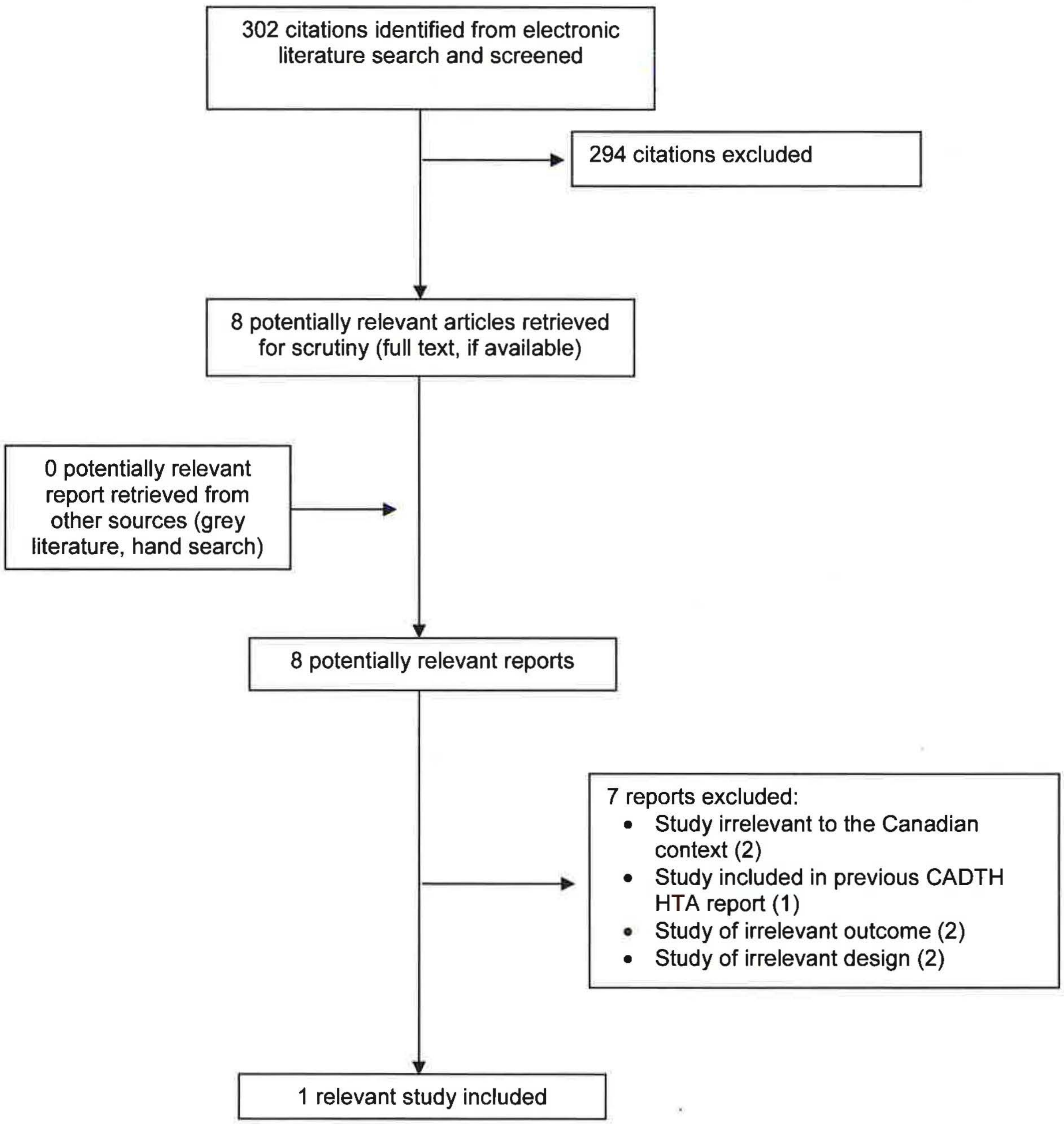
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Studies

Table 2: Characteristics of Included Primary Study

First Author, Publication Year, Country, Funding	Study Design and Analysis	Patient Characteristics	Interventions	Comparators	Outcomes
Green et al., 2019[13] Canada Funding: Public	Prospective birth cohort study Multicentre Sample size calculation: No Cohort was from the MIREC program that recruited 2,001 pregnant women from 10 cities across Canada A subset of 610 mother-child pairs from 6 out of 10 cities of the MIREC study was selected for neurodevelopment testing of children at ages 3 to 4 years	Mothers: Pregnant women within the first 14 weeks of pregnancy Mean age (SD): 32.33 (5.07) years White: 90 % Married or common law: 97% Bachelor's degree or higher: 68% Employed at time of pregnancy: 88% Net income household > $70,000 CAD: 71%	Exposure to higher levels of fluoride determined by MUF or fluoride intake, and correlated with living area having CWF	Exposure to lower levels of fluoride determined by MUF or fluoride intake, and correlated with living areas having non-CWF	Primary outcome: – FSIQ (measuring global intellectual functioning) Other outcomes: – VIQ (measuring verbal reasoning and comprehension) – PIQ (measuring nonverbal reasoning, spatial processing, and visual-motor skills)

First Author, Publication Year, Country, Funding	Study Design and Analysis	Patient Characteristics	Interventions	Comparators	Outcomes
	Up to 241 mother-child pairs were excluded due to various reasons, leaving 369 mother-child with MUF, IQ, complete covariates and water fluoride data, and 400 mother-child pairs with fluoride intake, IQ, complete covariates and water fluoride data Two sets of measurements: By MUF By fluoride intake Statistical analysis: Multiple linear regression analyses	Smoked in trimester 1: 2% Secondhand smoke at home: 4% Alcohol consumption (drink/month): None: 83% < 1: 8% ≥ 1: 9 Parity (first birth): 46% Children: Female: 52% Mean age (SD) at testing: 3.42 (0.32) years Mean gestation (SD): 39.12 (1.57) weeks Mean birth weight (SD): 3.47 (0.49) kg	Maternal fluoride exposure[a] measurements: Mean MUF_{SG} (SD) – Total sample: 0.51 (0.36) mg/L – Non-fluoridated areas: 0.40 (0.27) mg/L – Fluoridated areas: 0.69 (0.42) mg/L Mean daily fluoride intake (SD) – Total sample: 0.54 (0.44) mg – Non-fluoridated areas: 0.30 (0.26) mg – Fluoridated areas: 0.93 (0.43) mg Mean water fluoride level (SD) – Total sample: 0.31 (0.23) ppm – Non-fluoridated areas: 0.13 (0.06) ppm – Fluoridated areas: 0.59 (0.08) ppm		

CWF = community water fluoridation; FSIQ = Full Scale IQ; IQ = intelligence quotient; MIREC = Maternal-Infant Research on Environment Chemicals; MUF = maternal urine fluoride; PIQ = performance IQ; VIQ = verbal IQ

[a] Fluoride came from any source, not specifically from CWF

Appendix 3: Quality Assessment of Included Study

Table 3: Quality Assessment of Included Prospective Cohort Study

NICE Checklist[14]	Green et al., 2019[13]	
Question	**Answer**	**Comment**
SECTION 1: POPULATION		
1.1 Is the source population or source area well described?	Yes	The Maternal-Infant Research on Environment Chemicals (MIREC) recruited pregnant persons within the first 14 weeks of pregnancy from 10 cities in Canada. A subset of 610 mother-child pairs in the MIREC study were recruited from 6 of 10 cities: Vancouver, Montreal, Kingston, Toronto, Hamilton, and Halifax. Children aged 3 to 4 years.
1.2 Is the eligible population or area representative of the source population or area?	Probably no	The recruitment of individuals, clusters or areas was not defined. It was unclear how 6 of 10 cities were chosen.
1.3 Do the selected participants or areas represent the eligible population or area?	Probably no	The method of selection of participants from the eligible population was not described. There was no report on the percentage of selected individuals or clusters who agreed to participate. Risk of selection bias.
SECTION 2: METHOD OF ALLOCATION TO INTERVENTION (OR COMPARISON)		
2.1 Selection of exposure (and comparison) group. How was selection bias minimized?	Acceptable	Fluoride exposure assessed by areas of fluoridation or non-fluoridation, and by mother urine fluoride and daily fluoride intake. There was no clear pre-defined level of fluoride exposure that was considered as low or high at start of the study. Mother-child pairs were sorted out based on maternal urine fluoride and fluoride intake after mother had been exposed to fluoride, and the knowledge of children's IQ might have affected the classification of exposure status of the mothers.
2.2 Was the selection of explanatory variables based on sound theoretical basis	Probably no	Evidence for the hypothesis that maternal fluoride exposure was associated with lower IQ in children was drawn from studies conducted in countries not applicable to the Canadian context (e.g., use of fluoridated salts, or water fluoride levels many folds higher

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NICE Checklist[14]	Green et al., 2019[13]	
		than the current recommended level in Canada)
2.3 Was the contamination acceptable low?	No	Fluoride exposure did not specifically come from CWF; it could be from other sources such as foods or swallowing toothpaste after toothbrushing.
2.4 How well were likely confounding factors identified and controlled?	Partially	Some confounding factors such as city, HOME score, maternal education, race/ethnicity, child sex, and prenatal secondhand smoke exposure were adjusted in the regression analysis.
2.5 Is the setting applicable to the Canadian context?	Yes	The study was conducted in Canada
SECTION 3: OUTCOMES		
3.1 Were the outcome measures and procedures reliable?	Partially	Mother urine fluoride concentration was analyzed using biochemical method previously published. Childrens' IQ was assessed using the Wechsler Preschool and Primary Scale of Intelligence, third Edition. The questionnaire used to collect the information on consumption of tap water and other beverages (tea, coffee) and the methods to estimate and calculate fluoride intake were not validated. Self-reported of dietary intake tends to be an unreliable measure.
3.2 Were the outcome measurements complete?	No	Results form all recruited participants were not reported. Over one third were excluded due to missing data. Unclear if missing IQ data from excluded children could affect the findings.
3.3 Were all the important outcomes assessed?	Yes	Full Scale IQ, verbal IQ and performance IQ were measured.
3.4 Was there a similar follow-up time in exposure and comparison groups?	Probably not	Unclear about the period of fluoride exposure of women. Some women might have a lifetime exposure, while others might just have exposure during pregnancy.
3.5 Was follow-up time meaningful?	Yes	All included children had lived in the areas since birth.
SECTION 4: ANALYSES		
4.1 Was the study sufficiently powered to detect an intervention effect (if one exists)?	Not reported	The study did not perform any sample calculation to obtain sufficient power to detect an intervention effect.
4.2 Were multiple explanatory variables considered in the analyses?	Yes	Two measures of fluoride exposure (maternal fluoride urine and fluoride intake) were used in the analyses for the association between fluoride exposure and children's IQ.

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NICE Checklist[14]	Green et al., 2019[13]	
4.3 Were the analytical methods appropriate?	Probably Yes	Linear regression analyses were adjusted with some confounding factors. Multiple analyses of the intervention-outcome relationship (both unadjusted and adjusted data) were reported.
4.4 Was the precision of association given or calculable? Is association meaningful?	Probably yes	Test statistics and associated *P* values reported for all analyses. R-squared values for linear regression were not reported. Unclear if association was meaningful.
SECTION 5: SUMMARY		
5.1 Are the study results internally valid (i.e., unbiased)?	No	High risk of bias due to selection of participants, classification of intervention, confounding, missing data, and measurement of outcomes
5.2 Are the findings generalizable to the source population (i.e., externally valid)?	Probably not	Although the study was conducted in Canada, there was a risk of selection bias of the participants into the sample. The findings could not be generalizable to the entire Canadian population.

CWF = community water fluoridation; HOME = Home Observation for Measurement of the Environment; IQ = intelligence quotient

Appendix 4: Main Study Findings and Author's Conclusions

Table 4: Summary of Findings of Included Primary Study

Main Study Findings	Author's Conclusions
Green et al., 2019[13]	
Children's intellectual ability measurements[a] Mean FSIQ (SD) – Total sample: 107.16 (13.26) Boys: 104.61 (14.09) Girls: 109.56 (11.96) – Non-fluoridated areas: 108.07 (13.31) Boys: 106.31 (13.60) Girls: 109.86 (12.83) – Fluoridated areas: 108.21 (13.72) Boys: 104.78 (14.71) Girls: 111.47 (11.89) **Associations between fluoride exposure variables (MUF_{SG}, daily fluoride intake, or water fluoride concentration) and FSIQ** Measurements with MUF_{SG} Unadjusted estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 mg/L MUF_{SG} – Total sample: -2.60 (-5.80 to 0.60) Boys: -5.01 (-9.06 to -0.97) Girls: 2.23 (-2.77 to 7.23) Adjusted[b] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 mg/L MUF_{SG} – Total sample: -1.95 (-5.19 to 1.28) Boys: -4.49 (-8.38 to -0.60) Girls: 2.40 (-2.53 to 7.33) Adjusted[b] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 0.33 mg/L MUF_{SG} (a value spanning the interquartile range between 25th to 75th percentiles) – Total sample: -0.64 (-1.69 to 0.42) Boys: -1.48 (-2.76 to -0.19) Girls: 0.79 (-0.83 to 2.42) Adjusted[b] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 0.70 mg/L MUF_{SG} (a value spanning 80th central range between 10th to 90th percentiles) – Total sample: -1.36 (-3.58 to 0.90) Boys: -3.14 (-5.86 to -0.42) Girls: 1.68 (-1.77 to 5.13) *Measurements with daily Fluoride Intake* Unadjusted estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 mg of daily fluoride intake – Total sample: -3.19 (-5.94 to -0.44) Adjusted[c] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 mg of daily fluoride intake – Total sample: -3.66 (-7.16 to -0.15)	*"In this study, maternal exposure to higher levels of fluoride during pregnancy was associated with lower IQ scores in children aged 3 to 4 years. These findings indicate the possible need to reduce fluoride intake during pregnancy."[13]* p. E1

Main Study Findings	Author's Conclusions
Adjusted[c] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 0.62 mg of daily fluoride intake (a value spanning the interquartile range between 25th to 75th percentiles) – Total sample: -2.26 (-4.45 to -0.09) Adjusted[c] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1.04 mg of daily fluoride intake (a value spanning 80th central range between 10th to 90th percentiles) – Total sample: -3.80 (-7.46 to -0.16) *Measurements with water fluoride concentration* Unadjusted estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 ppm (or 1 mg/L) of water fluoride concentration – Total sample: 3.49 (-9.04 to 2.06) Adjusted[c] estimates, regression coefficient *B* (95% CI) of FSIQ for an increase of 1 ppm (or 1 mg/L) of water fluoride concentration – Total sample: -5.29 (-10.39 to -0.19) **Sensitivity analyses predicting the associations between an increased of 1 mg/L of MUF_{SG} and FSIQ in boys, regression coefficients *B* (95% CI)** – Model A[d]: -4.49 (-8. 8.38 to -0.60) – Model A adjusting for lead: -4.61 (-8.50 to -0.71) – Model A adjusting for mercury: -5.13 (-9.16 to -1.10) – Model A adjusting for perfluorooctanoic acid: -4.57 (-8.21 to -0.50) – Model A adjusting for arsenic: -4.44 (-8.35 to -0.54) – Model A adjusting for manganese: -4.55 (-8.42 to -0.69) – Model A adjusting for secondhand smoke exposure: -4.18 (-8.06 to -0.30) – Model A excluding two boys with FSIQ lower than 60: -4.11 (-7.89 to -0.33) – Model A adjusting for creatinine: -6.96 (-8.56 to -1.36) **Associations between fluoride exposure variables (MUF_{SG}, daily fluoride intake, or water fluoride concentration) and PIQ** *Measurements with MUF_{SG}* Unadjusted estimates, regression coefficient *B* (95% CI) of PIQ for an increase of 1 mg/L MUF_{SG} – Total sample: -5.81 (-9.31 to -2.30) Boys: -8.11 (-13.29 to -4.32) Girls: -0.56 (-6.09 to 4.97) Adjusted[b] estimates, regression coefficient *B* (95% CI) of PIQ for an increase of 1 mg/L MUF_{SG} – Total sample: -1.24 (-4.88 to 2.40) Boys: -4.63 (-9.01 to -0.25) Girls: 4.50 (-1.02 to 10.05) *Measurements with daily Fluoride Intake* Unadjusted estimates, regression coefficient *B* (95% CI) of PIQ for an increase of 1 mg daily fluoride intake – Total sample: -5.75 (-8.74 to -2.76) Adjusted[c] estimates, regression coefficient *B* (95% CI) of PIQ for an increase of 1 mg daily fluoride intake – Total sample: -2.74 (-6.82 to 1.34) *Measurements with water fluoride concentration*	

Main Study Findings	Author's Conclusions
Adjusted[c] estimates, regression coefficient *B* (95% CI) of PIQ for an increase of 1 ppm (or 1 mg/L) of water fluoride concentration – Total sample: -13.79 (-18.82 to -7.28) **Associations between fluoride exposure variables (MUF_{SG}, daily fluoride intake, or water fluoride concentration) and VIQ** *Measurements with MUF_{SG}* Unadjusted estimates, regression coefficient *B* (95% CI) of VIQ for an increase of 1 mg/L MUF_{SG} – Total sample: 1.28 (-1.87 to 4.43) Boys: -0.21 (-4.19 to 3.77) Girls: 4.78 (-0.14 to 9.70) Adjusted[b] estimates, regression coefficient *B* (95% CI) of VIQ for an increase of 1 mg/L MUF_{SG} – Total sample: -1.60 (-4.74 to 1.55) Boys: -2.82 (-6.62 to 0.98) Girls: 0.50 (-4.32 to 5.33) *Measurements with daily Fluoride Intake* Unadjusted estimates, regression coefficient *B* (95% CI) of VIQ for an increase of 1 mg daily fluoride intake – Total sample: -0.03 (-2.71 to 2.64) Adjusted[c] estimates, regression coefficient *B* (95% CI) of VIQ for an increased of 1 mg daily fluoride intake – Total sample: -3.08 (-6.40 to 0.25) *Measurements with water fluoride concentration* Adjusted[c] estimates, regression coefficient *B* (95% CI) of VIQ for an increased of 1 ppm (or 1 mg/L) of water fluoride concentration – Total sample: 3.37 (-1.50 to 8.24)	

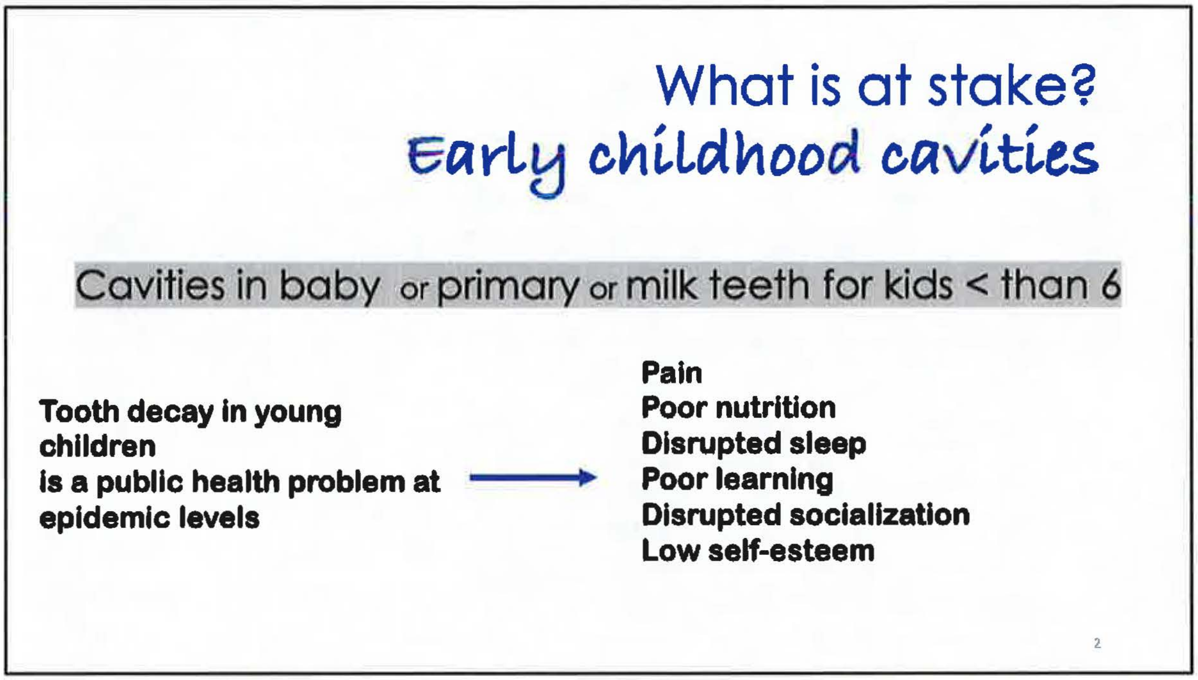
CWF = community water fluoridation; FSIQ = full Scale IQ; HOME = Home Observation for Measurement of the Environment; IQ = intelligence quotient; MUF_{SG} = maternal urine fluoride concentration adjusted for specific gravity; ppm = part per million (or mg/L); PIQ = performance IQ; SD = standard deviation; VIQ = verbal IQ

[a] Children intellectual ability was assessed using the Wechsler Preschool and Primary Scale of Intelligence, 3rd edition (WPPSI-III)[16] The WPPSI-III contains 14 subtests and two age ranges (from 2 years and 6 months to 3 years and 11 months, and from 4 years and 0 months to 7 years and 3 months). For children in the first age range, FSIQ, VIQ and PIQ scores are obtained from four core subtests. Seven core subtests are for children in the second age range.

[b] Adjusted for city, HOME score, maternal education, race/ethnicity, and child sex interaction.

[c] adjusted for city, HOME score, maternal education, race/ethnicity, child sex interaction, and prenatal secondhand smoke exposure.


Community
Water
Fluoridation
Cynthia Weijs PhD
University of Calgary
October 29, 2019
1



First off, when young children have cavities in their primary teeth they will be more likely to have cavities in their permanent teeth. And so for the long term not having cavities in baby teeth is better.

But of more immediate concern is that young children with tooth decay are suffering.

Poor oral health can also have dramatic effects on our overall health and quality of life- for example- Early childhood decay (cavities in primary or baby teeth) is the most common childhood disease, and is increasing in Canada- Early childhood decay affects

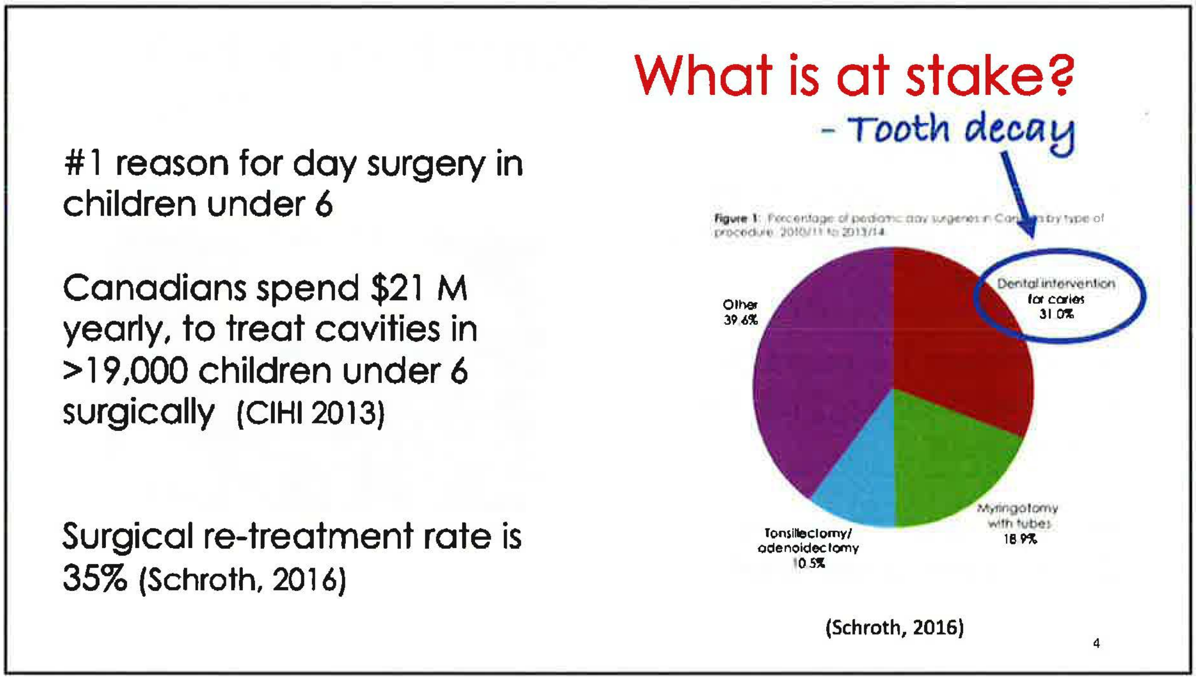
What is at stake?
- Tooth decay

- ~ $4-6 M spent on Emergency Dept visits for tooth pain related to decay in Alberta
- For children 1-5 years old those visits cost ~ $1.2-1.8 million/year
- But, ED's don't provide dental care or services!!

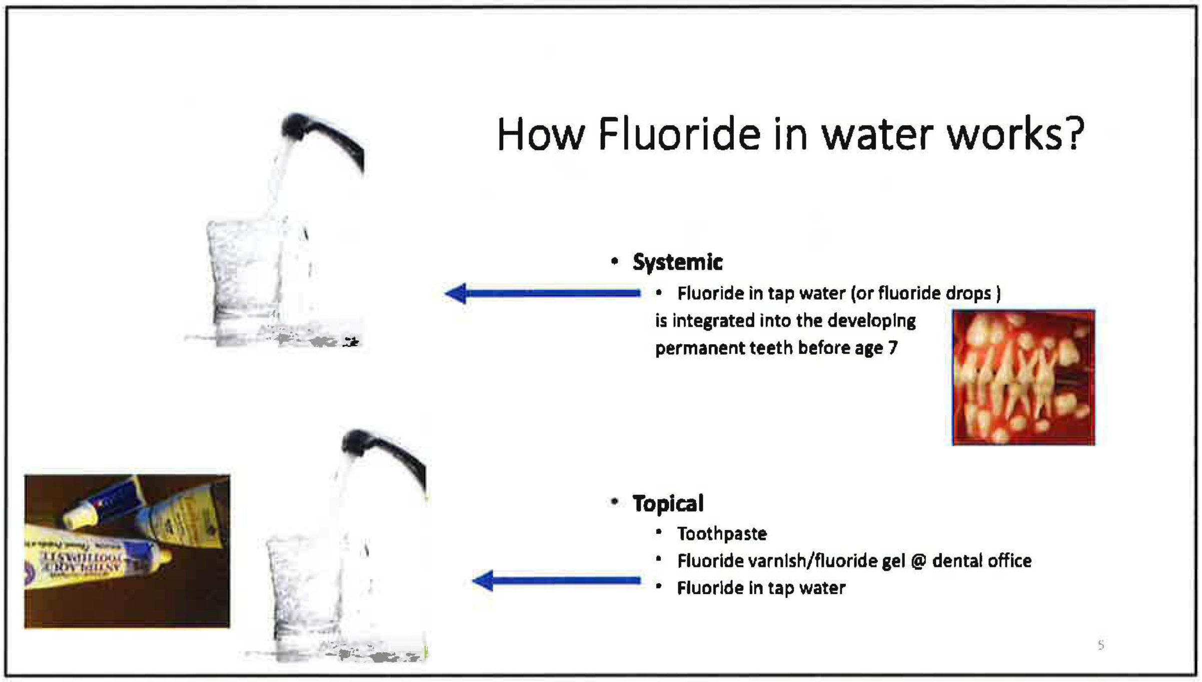
(Figueiredo et al, 2017)

3

When we have very good access to hospitals and physicians on the one hand and poor access to dental services for many on the other hand, we see some very costly and inefficient trends. Albertans spend between $4 - 6 million yearly on Emergency Department visits for tooth complaints that arise from decay and infection. And a significant portion of that is for young children with primary tooth decay. However, emergency depts don't generally provide dental care, so these young patients will leave with a prescription for pain killers and/or antibiotics and a recommendation to seek out a dentist. They won't receive any dental treatment at an ED but physicians still need to bill the system for the visit of course. So that is costly and ineffective care.

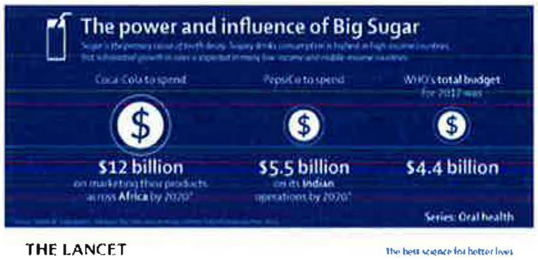


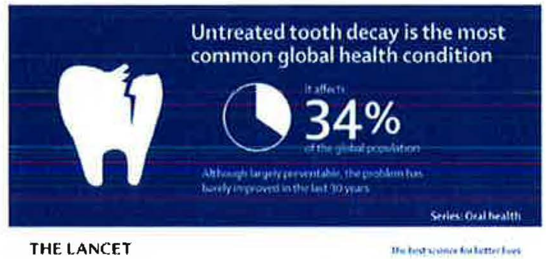
Another inefficiency is in the treatment of severe tooth decay among very young children. Treatment of tooth decay under general anaesthesia is the # 1 reason for day surgery in children under 6 years old.
Canadians spend **$21 million**/year treating cavities in this way.
That estimate doesn't count Anesthesiologist/dental surgeon fees, parent's travel, lost work costs, or costs of similar surgeries carried out in private dental offices. So it is only a hint at what we are actually spending. And retreatment rates are ~35%- so one third of those may undergo the surgery a second time!
High risk (general anaesthetic is not recommended by AAPD and FDA for 2-4 year olds where it is not necessary) and poor outcomes (35% of cases need retreatment within 2 years).



The benefit of fluoride comes mostly from topical use- when low doses of fluoride continually mix with saliva, and bathe the teeth- hardening your teeth to prevent decay, and remineralizing teeth where cavities have started. Importantly, with respect to young children, the topical effect of fluoridated water is a key reason why this intervention reduces 50% of the surgeries that treat decay.

Toothpaste is a challenge for parents of young children. Because it has a very high fluoride content. Children cannot reliably spit toothpaste out until they are 6 or 7 years old, and swallowing toothpaste increases chances for dental fluorosis. Hence the recommendations to use very small amounts. The systemic effects of water fluoridation are indeed minimal, but its topical effects are significant, and it works without a person having to think about using it and no need for parental supervision of water intake.





The Lancet- July 2019

6

Why we have high decay rates among young children despite having fluoride in the water for so many years.

Fluoride, while an important piece, is not a simple fix for dental decay. We are in the midst of an epidemic of decay that has been highlighted by the The Lancet in July 2019. Essentially the key messages are that the private dental model has not been successful and cannot be successful in achieving sustained improvements in population oral health or address the persistent inequalities in oral health. Childhood decay especially, is a community/public health problem and like similar problems, it is best addressed at the community level by every possible option (municipal and provincial) at this point in time.

Education not fluoridation: The answer to this problem is not simply parent education. Education has not been shown to have the long term impact needed. As council likely well knows, parent's role in looking after their children's teeth needs to be understood in the context of social factors that affect all lifestyle behaviours. The success of the Childsmile program in Scotland rests on how well they can continue to support families in the community.

Other factors identified in the Lancet are the problem of significant amounts of sugar in our food system and the influence of the sugar industry. This is a fundamental, society-level issue, not one we can expect individual parents to deal with without support at the community and population level.

Early childhood cavities are not fundamentally about access to dental care, but rather they are about community-level support for the behaviours that prevent cavities (similar to breastfeeding, vaccination, and other well child initiatives in public health). If access to care was the answer, the children of Calgarians who have dental plans (~70% of Albertans) would not be undergoing surgery for treatment. The focus needs to shift to community-level prevention initiatives that needs to include public health, private dentistry and community organizations.

AHS has several small and targeted programs for dental public health (e.g., fluoride varnish). Beyond that, there is very little capacity for prevention efforts for children under 6 either in dental public health or the private dental health system. It is hard to focus on prevention in the face of so many treatment needs.

CPS2019-0965
Attachment 3

Oral Health
Action Plan

2016

Alberta Health Services

This document was produced through collaborative efforts of the AHS Provincial Oral Health Office Team:

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Executive Summary

Oral health is an essential part of overall health and impacts individuals' quality of life and well-being. Access to dental care correlates directly with good oral health. The opposite is also true: lack of access to dental care results in poor oral health, affecting individuals' physical, social/emotional and economic health. Signs and symptoms include disabling pain, recurring infections, and a dysfunctional dentition. Impacts range from delayed growth in children, to exacerbation of chronic diseases such as diabetes in adults. Untreated dental disease limits children's ability to learn, and adults to gain and maintain employment. The dental care system in Canada, which mainly operates as a private fee-for-service system, poses accessibility barriers to certain groups of the population. Timely access to preventive services, and to treatment services at early stages of oral disease is essential to achieving and maintaining good oral health throughout life. Cost of care is a significant factor in accessing dental services. Inability to pay, lack of employment benefits, or ineligibility for public health benefits contributes to poor oral health and to an uneven distribution of disease among Canadians. This oral health inequity, where low income and working poor are disadvantaged by their social economic status, makes them the most vulnerable group for poor oral health.

The oral health component of the *Canadian Health Measures Survey* identifies that the cost of care limits access to dental care and consequently impacts the oral health status of the Canadian population. This national oral health reality is also observed in Alberta. In particular, poverty and lack of dental insurance not only limits access to dental care but further limits an individual's ability to exercise control over their life and to secure employment. The lack of these determinants of health contributes to oral health inequity. In Alberta, poverty affects 12% of the population. Among children under 18 years of age, 11% live in poverty, and more than half of them are under the age of six.

Similar to other Canadian provinces, the Alberta Government provides basic oral health care benefits for some low income Albertans and/or their dependents. Each program has specific eligibility criteria based on income, employment status, age, or disability. Despite these initiatives, not all vulnerable Albertans are eligible to receive dental benefits and/or dental benefits may not meet all their needs. Individuals with limited access to oral health care rely on non-dental health professionals and hospital facilities to alleviate the symptoms of pain and infections associated with oral disease. While hospital emergency departments can provide temporary measures such as relief for dental pain and infection, they do not provide definitive dental care. The use of emergency departments as the primary source for dental care is neither ideal nor efficient, representing a misuse of health care resources.

In Alberta, addressing the oral health needs of the population became more provincially focused with the appointment of the Alberta Health Services (AHS) Provincial Dental Public Health Officer and Provincial Oral Health Manager in 2009 followed by the development of a provincial *Oral Health Action Plan (OHAP)* in 2010. The current *OHAP 2016* document updates the initiatives and objectives to meet the oral health needs of Albertans and to ensure sustainability of the initiatives currently implemented.

The Provincial Oral Health Office (POHO) is responsible to lead and facilitate initiatives to improve the oral health status of Albertans, with special attention to those groups of the population that are more vulnerable. Within AHS, POHO is part of Chronic Disease Prevention and Oral Health; Healthy Living; and Population, Public and Aboriginal Health. POHO is also supported by the Council of Public Health Physicians. Overall clinical leadership and oversight of POHO is provided by the Provincial Dental Public Health Officer with support from 0.4 FTE Associate Dental Public Health Officers. Operational leadership of the provincial prevention and promotion domains within POHO is provided by the Provincial Oral Health Manager and 2.5 FTE team leads. The Manager/ Division Chief, Dental Public Health Clinics has responsibility for clinical and operations of the treatment domain of POHO. With POHO's vision "to improve the oral health status of Albertans," we follow our mission "to provide leadership and strategic direction to respond to Albertan's oral health needs."

POHO organizes the oral health initiatives established by OHAP 2016 into four domains to reflect the scope of initiatives for public oral health in Alberta. The domains are identified as follows: health promotion; prevention services; treatment services; and research and surveillance. Each domain is correlated to specific initiatives, objectives, and indicators for OHAP 2016.

In line with POHO's vision, mission and guiding principles, OHAP 2016 takes these actions:

- addressing the burden of oral disease for Albertans focusing on vulnerable groups in the population
- contributing to healthy lifestyles by addressing risk factors for oral health that arise from social, economic, environmental, and behavioural factors
- supporting the ongoing development of standardized public oral health services that equitably improve oral health
- advocating and developing oral health policies to integrate into the broader systems of social, economic and environmental determinants of health

Through leadership, POHO collaborates with government leaders, policy makers, organizations, AHS Zones and communities to successfully oversee the delivery of the OHAP 2016 initiatives and consistently utilize scientific evidence-based dentistry in its decision making.

Background

Oral health is an essential part of overall health and impacts quality of life and well-being. Access to dental care correlates directly with good oral health. The opposite is also true: lack of access to dental care results in poor oral health (CAHS, 2014). Dental care in Canada operates primarily as a private fee-for-service system. Timely access to preventive and treatment services at early stages of oral disease is critical to achieve and maintain good oral health throughout life.

Cost of care is a significant factor in accessing dental services (Health Canada, 2010). Most Canadians pay for oral health services through employment benefits or they pay for it themselves. Sixty-two per cent of Canadians have private insurance, 32% of the population has no dental insurance and 6% access the limited resources of publicly funded dental services (Health Canada, 2010). Inability to pay, lack of employment benefits, or ineligibility for public health benefits contributes to poor oral health and to an uneven distribution of disease among Canadians. This oral health inequity where low income and working poor are disadvantaged by their social economic status makes them the most vulnerable group for poor oral health. National data also reports that lower middle income families in Canada are facing economic barriers to dental care (Ramraj, Lawrence, Dempster, & Quinonez, 2013).

Improving Access to Oral Health Care for Vulnerable People Living in Canada (CAHS, 2014) identifies the following most vulnerable Canadians:

- children in low income families
- adult workers without employment-related dental insurance
- elderly people living in institutions and/or with a low income
- Aboriginal people
- refugees and immigrants
- individuals with disabilities
- people living in rural and remote regions

The oral health component of the *Canadian Health Measures Survey* identifies that the cost of care impedes access and consequently impacts the oral health status of the Canadian population. (Health Canada, 2010) The following list conveys the impact of cost on access to dental care:

- Seventeen per cent of the general population in Canada avoided going to a dental professional because of cost (Health Canada, 2010).
- Sixteen per cent of the general population in Canada avoided having the full range of recommended treatment due to the cost (Health Canada, 2010).
- Thirty-four per cent of the lowest income Canadians avoided going to a dental professional because of cost; while 9% of the highest income Canadians avoided going to a dental professional because of cost (CAHS, 2014).
- Approximately 50% of people in the lowest income group reported having no insurance (CAHS, 2014).

- Twenty-six per cent of children and adolescents without insurance avoided going to a dental professional due to cost versus 6% with dental insurance (CAHS, 2014).
- Forty-six per cent of adults without dental insurance avoided going to a dental professional due to cost versus 10% with insurance (CAHS, 2014).
- Nineteen per cent of the elderly without dental insurance avoided going to a dental professional due to cost versus 6% with insurance (CAHS, 2014).

Poor oral health throughout life can have substantial consequences affecting not only individuals, but also our society and the health-care system. For the vulnerable populations, the impact is further exacerbated by the lack of access to oral health care (CAHS, 2014). The following are some of the major impacts of poor oral health:

Health Impacts (Rowan-Legg, 2016)

- increased risk of new decay in primary and permanent dentition
- limited diet choices
- trouble eating, sleeping, and speaking
- risk of delayed physical growth and development
- aggravation of pre-existent chronic health conditions and contribution to new ones
- repeated infections and fever

Social Impacts (US Department of Health and Human Services, 2000)

- loss of school days and restricted activities
- diminished oral health related to quality of life and well-being
- embarrassment, and diminished self-esteem and sociability

Economic Impacts (CAHS, 2014)

- loss of work days
- increased treatment costs
- inappropriate utilization of non-dental health professionals and hospital facilities

Similar to the rest of Canada, poverty in Alberta directly impacts poor oral health and affects 12% of the population. Eleven per cent of children under the age of 18 live in poverty, with more than half under the age of six. A report on the needs of poor Albertans identifies that lack of access to dental care limits the ability to exercise control over one's life and secure employment (Hudson, 2014). As in other Canadian provinces, the Alberta Government provides basic oral health-care benefits for some low income Albertans and/or their dependents. Each program has eligibility criteria based on income, employment status, age, or disability (Alberta Government, 2016). Despite these initiatives, not all vulnerable Albertans are eligible for dental benefits and/or dental benefits may not meet all their needs (Hudson, 2014). Individuals who cannot access private or publicly funded oral health care rely on non-dental health professionals and hospital facilities to alleviate pain and infections associated with oral diseases (Alberta Health, 2015).

The *2015 Health Trends Alberta* report shows that dental problems not associated with trauma place an unnecessary burden on hospital emergency departments (EDs). In a five-year period, there were 37,000 ED visits in Alberta for toothaches to manage pain and infection. According to the same report, "Each ED visit is estimated to cost the health-care system approximately $150 to $225." It indicates that the ED visits for dental problems are more common among individuals in the lowest income quintile (Alberta Health, 2015). While EDs provide temporary measures such as relief for pain and infection, they do not provide definitive dental care and fail to resolve underlying dental problems (CAHS, 2014; LaPlante, Singhal, Maund, & Quinonez, 2015).

Oral Health Action Plan

Addressing the oral health needs of Albertans has become more provincially focused with the appointment of the Provincial Dental Public Health Officer and Provincial Oral Health Manager for AHS in 2009. The establishment of these provincial leadership roles led to the Provincial Oral Health Action Plan (OHAP) 2010 framework. OHAP 2010 recommends standardized, evidence-based prevention and treatment services for children, seniors, and low income individuals across the province to address oral health inequities. In alignment with the plan, AHS Zones implement services within existing public oral health resources to achieve the OHAP 2010 objectives. The present document, *Oral Health Action Plan 2016*, updates initiatives and objectives to meet population needs and ensures sustainability. In addition, the updated plan moves forward with a comprehensive population health approach and expansion of the initiatives.

Provincial Oral Health Office

Who We Are

The Provincial Oral Health Office (POHO) is responsible to lead and facilitate initiatives to improve the oral health status of Albertans, with special attention to groups of the population that are more vulnerable. Within AHS, POHO is part of Chronic Disease Prevention and Oral Health; Healthy Living; and Population, Public and Aboriginal Health. POHO is also supported by the Council of Public Health Physicians. Overall clinical leadership and oversight of POHO is provided by the Provincial Dental Public Health Officer with support from 0.4 FTE Associate Dental Public Health Officers. Operational leadership of the provincial prevention and promotion domains within POHO is provided by the Provincial Oral Health Manager and 2.5 FTE team leads. The Manager/ Division Chief, Dental Public Health Clinics has responsibility for clinical and operations of the treatment domain of POHO. This consists of two Dental Public Health Clinics in Calgary (14.18 FTEs) and the Dental Outreach Program (three satellite clinics in the North Zone) operated by the School of Dentistry, University of Alberta.

POHO engages a variety of stakeholders within and external to AHS to implement OHAP initiatives. Standard dental prevention services are managed and delivered by AHS Zones to meet local needs including resource capacity, population distribution, and population characteristics such as culture and language. Currently, there are approximately 59 FTE Registered Dental Assistants and Dental Hygienists providing preventive services to preschool and school age children in the province. The University of Alberta is an external stakeholder delivering services through the Dental Outreach Program in three northern communities. Additional stakeholders are identified in the section "OHAP 2016 Domain Initiatives".

To achieve our vision "to improve the oral health status of Albertans," we follow our mission "to provide leadership and strategic direction to respond to Albertans' oral health needs." A set of guiding health principles is used to make decisions for OHAP initiatives and to achieve our vision and mission. Diagram 1 (pg. 10) outlines the POHO perspective.

Core Functions

To achieve POHO's vision, we employ core functions that align with elements of population and public health. We use these core functions to plan and develop OHAP 2016 initiatives. These initiatives and their objectives are further strengthened by their alignment with the *AHS 2014-2017 Health Plan and Business Plan* to provide appropriate care, develop partnerships for better health, and create a sustainable public oral health-care system (Alberta Health Services, 2014). We identify seven core functions essential to addressing the oral health of Albertans:

- oral health surveillance
- evidence-based dentistry
- standardized prevention and treatment services
- strong oral health partnerships
- monitoring and evaluation of initiatives

- responding to emerging issues
- oral health advocacy

For each core function, we develop operating processes and systems for quality management. Within these systems, POHO adheres to AHS organizational values of respect, accountability, transparency, engagement, safety, learning, and performance. Table 1 outlines POHO core functions, OHAP 2016 objectives, and the AHS *Health Plan* and *Business Plan*.

VISION | MISSION | PRINCIPLES

Provincial Oral Health Office

To improve the oral health status of Albertans

To provide leadership and strategic direction to respond to Albertans' oral health needs

Every Albertan deserves good oral health as part of good health

Access to oral health care improves health, well-being, and quality of life

Partnership and collaboration create a supportive environment for oral health

Evidence-based dentistry enables a cost effective utilization of resources

Oral health standards of care ensure quality services

Leadership and communication improve capacity to meet public health needs

Diagram 1: POHO Vision, Mission and Guiding Principles

POHO Core Functions	OHAP 2016 Objectives	*AHS Health Plan and Business Plan* (Alberta Health Services, 2014)
ORAL HEALTH SURVEILLANCE EVIDENCE-BASED DENTISTRY STANDARDIZE PREVENTION AND TREATMENT SERVICES STRONG ORAL HEALTH PARTNERSHIPS MONITORING AND EVALUATION OF INITIATIVES RESPONDING TO EMERGING ISSUES ORAL HEALTH ADVOCACY	Target disadvantaged preschool children and provide the standardized provincial fluoride varnish service Provide comprehensive dental treatment to low income children and adults in Alberta without private dental insurance or government funded dental benefits Target disadvantaged school children and provide the standardized provincial fluoride varnish service Target disadvantaged school children and provide the standardized provincial dental sealant service Provide comprehensive dental treatment services to communities in northern Alberta	STRATEGY **Bringing appropriate care to the community** GOAL 1 Build a strong, integrated community and primary health care foundation to deliver appropriate, accessible, and seamless care
	Engage with internal/external partners to provide Albertans with access to oral health information Inform stakeholders about the oral health status of Albertans Support Albertans' access to fluoridated drinking water Promote measures that support improvement of oral health for seniors in care	STRATEGY **Partnering for better health outcomes** GOAL 2 Actively engage Albertans as partners and provide them with the support they need to enhance control over the factors that affect their health and the health of their families GOAL 3 Advance the adoption of evidence-informed practices in the delivery of quality services across the continuum through partnerships with providers, academic institutions, physicians, and others
	Expand the number of health-care providers and facilities receiving training for daily oral hygiene in continuing care Increase the current utilization of preventive and treatment services by target population Collect oral health information on the Alberta population to support planning, implementation, and evaluation Research oral health issues that impact the oral health status of the population	STRATEGY **Achieving health system sustainability** GOAL 4 Continue to build a sustainable, quality health system that is patient-centred, and driven by outcomes and informed by evidence

Table 1: POHO Core Functions, OHAP 2016 Objectives and AHS Health Plan and Business Plan 2014-2017

Employing a Population Health Approach in OHAP

We use a population health approach to focus on the interrelated conditions and factors that influence the oral health of Albertans, to identify systematic variations, and to utilize this subsequent knowledge for addressing oral health inequities. The Public Health Agency of Canada (PHAC) outlines eight elements of a population health approach that complement POHO core functions for developing OHAP initiatives (Public Health Agency of Canada, 2013). Through this approach, the initiatives target population groups at risk for oral disease, reducing inequities, and improving the oral health status of Albertans.

Diagram 2: Population Health Approach (Public Health Agency of Canada, 2013)

The following are eight elements of a population health approach with corresponding examples of how POHO employs each of them.

Population Health Approach	Description of Elements	POHO Examples
Focus on oral health of population	Assess oral health status and oral health status inequities over the lifespan at the population level	Provincial oral health surveillance
Address oral health determinants and their interactions	Measure and analyze the full range of factors, commonly referred to as the determinants of health, known to influence and contribute to oral health	Deprivation mapping to identify population sub-groups vulnerable to poor oral health outcomes
Base decisions on evidence	Use an approach that puts a body of information through a broad critical review process	Evidence-based standards for dental sealant services to prevent tooth decay
Increase upstream investments	Maximize impact by directing efforts and investments "upstream" to address root causes of oral health and illness	Community water fluoridation
Apply multiple interventions and strategies	Integrate multiple interventions and strategies across the oral health continuum	Preventive and treatment services Policy advocacy and development
Collaborate across sectors and levels	Share responsibility for health outcomes across multiple sectors and levels whose activities directly or indirectly impact oral health	Oversight of Dental Outreach Program through partnership with the University of Alberta and Alberta Health
Employ mechanisms for public involvement	Promote citizen participation in oral health improvement by providing public opportunities to contribute in meaningful ways to the selection of health priorities, the development of strategies, and the review of outcomes	Advocacy for community water fluoridation
Demonstrate accountability for oral health outcomes	Focus on oral health outcomes and determining the degree of change that can be attributed to interventions	Oral health dashboard Reports on Albertans' oral health

Table 2: Eight Elements of a Population Health Approach

OHAP Planning and Evaluation

POHO decision-making to plan OHAP initiatives considers the Equity Effectiveness Loop proposed by Tugwell (Tugwell, de Savigny, Hawker, & Robinson, 2006). The loop provides a framework for developing and evaluating population health interventions and policies that focus on narrowing the gap between rich and poor, using the best available evidence. This framework integrates the concepts of individual risk and socioeconomic status with intervention effectiveness from a population health perspective. The iterative loop emphasizes the importance of monitoring and re-assessing health initiatives after they are implemented to determine the impact on the burden of disease. The five steps in the loop follow a planning process cycle for development, implementation, and evaluation. Diagram 3 depicts Tugwell's Equity Effectiveness Loop (Tugwell, de Savigny, Hawker, & Robinson, 2006).

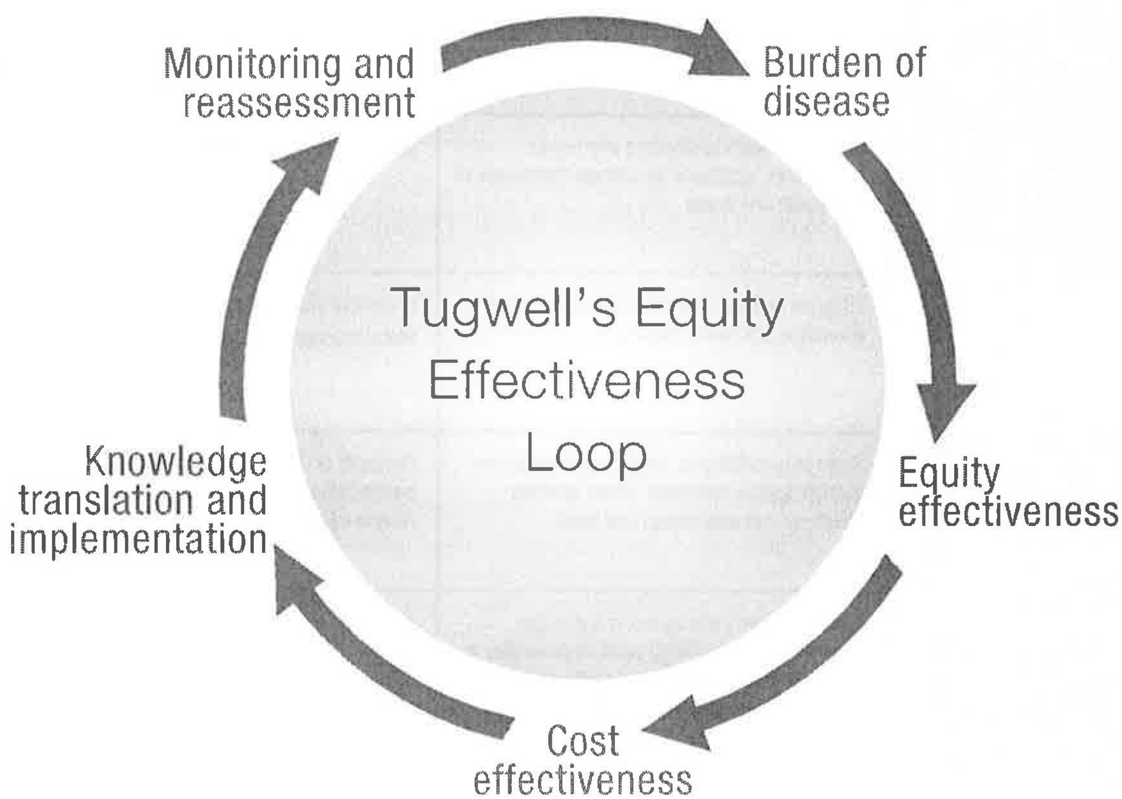

Diagram 3: Tugwell's Equity Effectiveness Loop

1. **Burden of disease:** to identify and assess possible causes of the burden of disease using oral health indicators and socioeconomic measures
2. **Community effectiveness**: to determine the benefits from an initiative once implemented in the community and estimate the reduction of the burden of diesease. The value of the initiative is influenced by the following modifiers:
   - diagnostic accuracy: accurately determining who is at risk using a population health approach
   - coverage/access: using the 5 "As" Approach: Availability, Accessibility, Affordability, Acceptability, and Accommodation
   - provider compliance: health-care providers follow standardized guidelines for service delivery
   - consumer support: consumers adopt the recommendations for oral health services. Service uptake is dependent on a consumer's time and financial resources, values, preferences, and attitudes
3. **Cost-effectiveness**: to determine the relationship between cost and effect, and ensure the initiative is delivered to those who benefit the most
4. **Knowledge translation and implementation:** to integrate evidence-based practices for feasibility, impact, and efficiency of oral health initiatives. Knowledge translation considers how oral health initiatives are affected by population characteristics, provider characteristics, context, and setting
5. **Monitoring and reassessment:** to provide ongoing monitoring of oral health initiatives using selected indicators to determine the impact and burden of disease

OHAP incorporates multiple initiatives that are progressing through different steps of the Equity Effectiveness Loop. Assessment throughout these steps informs evaluation:

- determines the need for an initiative
- determines if inputs and activities lead to expected outcomes
- identifies strengths and weaknesses for improvement
- monitors initiatives for attainment of objectives
- facilitates informed decision-making, priority setting, and resource allocation
- ensures the quality of initiatives to meet intended outcomes
- re-assesses needs and prioritizes future initiatives

Ethical Considerations in OHAP

In OHAP, we employ a population health approach to identify high risk groups in the population and standardize services to address oral health equity. The AHS policy *Appropriate Prioritization of* Access to Health guides us in ethical decision-making (Alberta Health Services, 2015). The policy outlines ethical principles for determining access to publicly funded oral health services in AHS. The principles include: moral equity, oral health equity, societal need, public confidence, transparency, and stewardship. Moral equity supports our vision that every Albertan has the right to good oral health. Oral health equity ensures vulnerable Albertans have access to oral health care. Societal need speaks to prioritizing services for high risk groups. We determine standards of care and adhere to them, ensuring public confidence and transparency for our decisions. As good stewards of public health resources, we utilize evidence-based dentistry proved to prevent and treat oral disease in populations.

Further support for ethical decisions comes from the Public Health Leadership Society Code of Ethics that guides practitioners in solving ethical dilemmas in public health practice. The ethical principles outlined in the leadership society document include the following (Public Health Leadership Society, 2002):

- protect and promote health
- address fundamental causes of health risks
- achieve community health with respect for individual rights
- provide opportunities for feedback from the community
- advocate that basic resources and conditions necessary for health are accessible to all
- collect information to implement effective policies and programs
- provide information to communities for decision-making
- act on information collected within the resources and mandate of public health
- incorporate diversity
- protect the confidentiality of information collected
- enhance physical and social environments
- ensure professional competence of employees
- engage in collaboration to build trust and effectiveness

We acknowledge practitioners are also directed by the professional codes of ethics of the Alberta Dental Association and College, the College of Registered Dental Hygienists of Alberta, and the College of Alberta Dental Assistants.

OHAP 2016 Domain Initiatives

We organize the OHAP 2016 oral health initiatives into four domains to reflect the scope of initiatives for public oral health in Alberta. The domains are: health promotion; prevention services; treatment services; and research and surveillance. Each domain is correlated to specific initiatives, objectives, and indicators for OHAP 2016, and is outlined in the following sections. The OHAP domains are depicted along with their descriptions in Diagram 4.

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance
To enable people to increase control over and improve their oral health. Oral health promotion goes beyond a focus on individual behaviour to address a wide range of socioeconomic and environmental factors	To provide preventive initiatives focused on addressing oral health inequities among disadvantaged Albertans	To provide dental treatment services focused on addressing oral health inequities among disadvantaged and geographically isolated Albertans	Collecting and analyzing information to improve the oral health of individuals, communities, and populations

Diagram 4: OHAP Domains

Domain: Health Promotion

The Ottawa Charter for Health Promotion includes five action areas that guide the OHAP 2016 oral health promotion initiatives (World Health Organization, 1986).

1. building healthy public policy
2. creating supportive environments
3. strengthening community action
4. developing personal skills
5. re-orienting health services

We engage in health promotion by working collaboratively with stakeholders, influencing decision-makers, impacting health determinants, and empowering and enabling Albertans to achieve good oral health. Implementing oral health promotion initiatives occurs in a variety of ways in response to stakeholder needs. Beyond prevention and treatment services, we recognize the need for broader health promotion strategies to support Albertans' oral health.

The following tables outline OHAP 2016 health promotion initiatives:

COMMUNITY WATER FLUORIDATION

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance

Support Albertans' access to fluoridated drinking water	
Indicator	Percentage of Alberta population with access to fluoridated drinking water
Accountability	POHO
Stakeholders	Community leaders/members/councils Alberta health professional associations AHS Medical Officers of Health AHS Zones AHS Environmental Public Health Community Water Fluoridation Committee
Actions	Sustain the Provincial Community Water Fluoridation Committee Provide water fluoridation information to municipalities on request Maintain accurate records of population access to fluoridation Maintain information and resources on water fluoridation that are available to the professions and the public

ORAL HEALTH INFORMATION

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance

Engage with internal/external partners to provide Albertans with access to oral health information

Indicator	Number of partnerships that result in the availability of oral health information
Accountability	POHO
Stakeholders	Alberta health professional associations AHS Comprehensive School Health AHS Environmental Public Health AHS Nutrition Services AHS Population Public and Aboriginal Health AHS Seniors Health AHS Zones My.Health.Alberta.ca Post-secondary educational institutions
Actions	Engage in collaborative partnerships to develop and share oral health information Provide information and resources to the public

SENIORS MOUTH CARE

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance

Promote measures that support improvement of oral health for seniors in care

Indicator	Adoption of policies Inclusion of daily oral health protocols in Continuing Care Health Service Standards
Accountability	POHO AHS Seniors Health
Stakeholders	AHS Seniors Health AHS Zones Alberta Health Ministry Alberta health professional associations Alberta senior population and family members Continuing care facilities
Actions	Advocate and develop standards for oral care

REPORTING ORAL HEALTH INDICATORS

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance

Inform stakeholders about the oral health status of Albertans

Indicator	Number of stakeholders provided with information on the oral health status of Albertans
Accountability	POHO
Stakeholders	AHS professionals AHS Population Health Infrastructure and Surveillance AHS Zones Alberta health professional associations Alberta population Non-government organizations Post-secondary educational institutions
Actions	Identify oral health indicators Develop and sustain the oral health dashboard Develop the POHO annual report

Domain: Prevention Services

OHAP 2010 was the basis for Zones to implement and manage oral health prevention services using evidence-based dentistry. OHAP 2016 uses information collected during the previous phase, evaluates results and reviews resources to re-define service indicators. Services include the application of fluoride varnish and dental sealants for children to prevent tooth decay, and daily mouth care to improve the general health and well-being for seniors. The Cochrane Review provides strong evidence that supports the effectiveness of fluoride varnish to reduce decay by 37% in primary teeth and 43% in permanent teeth (Marinho, Worthington, Walsh, & Clarkson, 2013). Dental sealants are also recognized as an effective preventive intervention, reducing tooth decay by 60% in children's permanent teeth (Truman, et al., 2002).

The need to support oral health for seniors residing in continuing care facilities remains a focus in OHAP 2016. Providing daily oral hygiene care for residents has beneficial effects for their oral and overall health (CAHS, 2014). A training program for health-care workers to deliver this care is available provincially. We work collaboratively with Zones to expand the modes for training and encourage the facilities and health-care workers to participate.

The following tables outline OHAP 2016 prevention service initiatives:

PRESCHOOL FLUORIDE VARNISH

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance

Target disadvantaged preschool children and provide the standardized provincial fluoride varnish service	
Indicator	10% to 20% of the population between the ages of 12 to 35 months receive their first fluoride varnish 55% to 75% of those enrolled in the program receive a second fluoride varnish application within the period of eligibility 30% to 50% of those enrolled in the program receive a third fluoride varnish application within the period of eligibility 20% to 40% of those enrolled in the program receive a fourth fluoride varnish application within the period of eligibility
Accountability	POHO AHS Zones
Stakeholders	AHS health professionals AHS Zones Community groups Disadvantaged Alberta families Primary Care Networks
Actions	Identify target individuals and communities Follow and adhere to the standard procedures in the *Provincial Preschool Oral Health Services Implementation Manual* Improve the completion rate of children receiving the service

SCHOOL FLUORIDE VARNISH

Health Promotion | **Prevention Services** | Treatment Service | Research & Surveillance

Target disadvantaged school children and provide the standardized provincial fluoride varnish service

Indicator	10% to 20% of Alberta school children in kindergarten and grades 1 to 2 receive their first fluoride varnish 80% to 100% of those enrolled in the service receive two FV applications in the given school year
Accountability	POHO AHS Zones
Stakeholders	AHS health professionals AHS Zones Alberta Education Disadvantaged Alberta families School administration and educators
Actions	Identify target schools Follow and adhere to the standard procedures in the *School Oral Health Services Implementation Manual* Improve the completion rate of children receiving the service

SCHOOL DENTAL SEALANTS

Health Promotion | **Prevention Services** | Treatment Services | Research & Surveillance

Target disadvantaged school children and provide the standardized provincial dental sealant

Indicator	85% to 100% of the students with a sealant referral plan receive all recommended sealants
Accountability	POHO AHS Zones
Stakeholders	AHS Zones AHS health professionals Alberta Education Disadvantaged Alberta families School administration and educators
Actions	Identify target schools Follow the standard procedures in the *School Oral Health Services Implementation Manual* Improve the completion rate of children receiving the service

CONTINUING CARE ORAL HEALTH STANDARD

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance

Expand the number of facilities trained to support the Continuing Care Health Service Standards for Oral Health

Indicator	Number of trainers trained to deliver the mouth care training Number of facilities participating in the program Number of health-care providers who received mouth care training
Accountability	AHS health professionals AHS Seniors Health AHS Zones Continuing care facilities POHO
Stakeholders	AHS health professionals AHS Seniors Health AHS Zones Continuing care facilities Residents in seniors facilities and their families Senior care providers
Actions	Follow the standard procedures in the *Mouth Care Training for Care Staff in Continuing Care, Train the Trainer Manual* Identify continuing care centres and other facilities that are eligible to receive the services

Domain: Treatment Services

Within AHS, we play an important role in addressing the need for dental treatment for underserved populations in Alberta. We oversee the provision of dental treatment through various models. One model is the Dental Public Health Clinics operating in the urban setting of Calgary. Another model is the Dental Outreach Program (DOP) operating in rural communities of northern Alberta. Both models utilize a reduced fee-for-service payment schedule. The expansion of dental public health treatment services throughout the province and among population sub-groups is critical to addressing dental health inequities and improving the oral health status of Albertans. Other models also exist as Zone initiatives.

Model 1: Dental Public Health Clinics (Calgary)

The Dental Public Health Clinics provide dental treatment for individuals that otherwise depend on the primary and acute care system for relief of pain and infection. Albertans who typically do not qualify for dental insurance or government benefits can receive comprehensive dental treatment at either the Northeast Clinic at Sunridge Medical Gallery or the Sheldon M. Chumir Health Centre. Albertans eligible for these dental services include the working poor, the unemployed, refugees, and the homeless population. In addition, dental services are provided to patients referred by the Home Parenteral Therapy Program to address their acute dental infection. Dental treatment services are provided by AHS health professionals and the clinics are open to all Albertans without geographic restrictions.

Model 2: Dental Outreach Program

The DOP provides dental treatment for individuals in remote and underserviced areas of Alberta where access to treatment is limited. Alberta Health provides funding support for the DOP while the University of Alberta is responsible for day-to-day management. POHO provides oversight for this arrangement. All members of the community can access full dental services and some specialized services such as children's dentistry. Undergraduate dental and dental hygiene students deliver supervised care for 30 weeks per year in the communities of McLennan, High Level, and La Crete.

The following tables outline OHAP 2016 treatment services initiatives:

DENTAL PUBLIC HEALTH CLINICS

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance

Provide comprehensive dental treatment to low income children and adults in Alberta without private dental insurance or government funded dental benefits

Indicator	Number of individuals and number of dental procedures delivered to patients annually Number of referrals received from primary and acute care sources Annual monetary value of services provided as per Alberta Blue Cross Usual and Customary Fee Schedule
Accountability	Chief of Dental Public Health Clinic POHO
Stakeholders	Alberta population Non-governmental organizations
Actions	Review and use information on client demographics and services delivered for ongoing provincial planning Identify strategies to manage increased demand for services

DENTAL OUTREACH PROGRAM

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance

Provide comprehensive dental treatment services to communities in northern Alberta

Indicator	Number and type of services provided
Accountability	POHO University of Alberta
Stakeholders	Alberta Health Alberta Health Services Communities of McLennan, High Level, and La Crete University of Alberta
Actions	Review the annual service report provided by the University of Alberta for the DOP to ensure contractual obligations are met

Domain: Research and Surveillance

We collect information on oral health conditions that impact the oral health, well-being, and quality of life of the population. The two major activities to achieve this initiative are research and surveillance. Health research is defined by the World Health Organization (WHO) as an instrument "to generate high quality knowledge which can be used to promote, restore, and/or maintain the health status of populations" (World Health Organization, 2001). The main objectives for the oral health research proposed by OHAP are the advancement of scientific knowledge and utilization of this knowledge to address oral health issues. Knowledge is translated to improve oral health and oral health equity. Additionally, our oral health research aims to benefit the political, administrative, social, and economic sectors in Alberta.

Surveillance, the second activity of this domain is "the ongoing systematic collection, analysis, and interpretation of outcome-specific data for planning, implementation, and evaluation of public health practice" (World Health Organization, 2016). The surveillance activities proposed by OHAP identify groups of the population at increased risk for dental diseases and ensure that our initiatives are delivered to those who need it the most to improve and protect their oral health status.

The following tables outline OHAP 2016 research and surveillance initiatives:

RESEARCH

Health Promotion | Prevention Services | Treatment Services | **Research & Surveillance**

Research oral health issues that impact the oral health status of the population	
Indicator	Number of research projects funded and completed
Accountability	AHS Public Health Surveillance and Infrastructure (PHSI) POHO
Stakeholders	AHS PHSI AHS Zones Alberta health professional associations Post-secondary institutions
Actions	Identify key surveillance issues to be researched Pursue opportunities for collaborative partnerships and funding

SURVEILLANCE

Health Promotion	Prevention Services	Treatment Services	Research & Surveillance

Collect oral health information on the Alberta population to support planning, implementation, and evaluation

Indicator	Number of surveillance activities completed
Accountability	AHS Public Health Surveillance and Infrastructure (PHSI) POHO
Stakeholders	AHS PHSI AHS Zones Alberta health professional associations Alberta population Post-secondary institutions
Actions	Pursue opportunities for funding and collaborative partnerships Utilize surveillance data in planning, implementing, and evaluating OHAP services Disseminate surveillance reports

Closing Remarks

In line with POHO's vision, mission, and guiding principles, OHAP 2016 establishes health promotion, prevention, treatment, research, and surveillance initiatives:

- addressing the burden of oral disease for Albertans, with a focus on vulnerable groups in the population
- contributing to healthy lifestyles by addressing risk factors for oral health that arise from social, economic, environmental, and behavioural causes
- supporting the ongoing development of standardized public oral health services that equitably improve oral health
- advocating for and developing oral health policies for integration into the broader systems of social, economic, and environmental determinants of health

Through leadership, POHO collaborates with government leaders, policy makers, organizations, AHS Zones and communities to successfully oversee the delivery of the oral health initiatives proposed by OHAP 2016 and consistently utilizes scientific evidence-based dentistry in its decision making.

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