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# Community Water Fluoridation Programs: A Health Technology Assessment — Ethical Considerations

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## Abbreviations

<b>AI</b>	adequate intake
<b>CWF</b>	community water fluoridation
<b>dmfs</b>	decayed, missing, and filled deciduous tooth surfaces
<b>dmft</b>	decayed, missing, and filled deciduous teeth
<b>HTA</b>	health technology assessment
<b>MAC</b>	maximum acceptable concentration
<b>ppm</b>	parts per million
<b>UL</b>	upper limit

## Introduction

Dental caries is a common public health problem in Canada,<sup>1</sup> and it affects about 57% of children aged six to 11 years and 59% of adolescents aged 12 to 18 years.<sup>2</sup> It has been estimated that the prevalence of coronal caries and the prevalence of root caries for Canadian adults aged 19 years and older is 96% and 20.3%, respectively.<sup>2</sup> Dental caries can result in pain, infection, premature tooth loss, and misaligned teeth.<sup>3</sup> Untreated dental caries in children are associated with poor overall growth, iron deficiency, behaviour problems, low self-esteem, and a reduction in school attendance and performance.<sup>4-9</sup> In pregnant women, periodontal diseases are risk factors for preterm low birth weight.<sup>10,11</sup> By adulthood, about 96% of Canadians have experienced dental caries.<sup>2</sup> In 2018, the cost of dental services was estimated to be approximately \$17 billion in Canada, about \$461 per Canadian, based on total national health expenditure estimated from both the private sector (\$15.2 billion) and public sector (\$1.8 billion).<sup>12</sup> Poor oral health is experienced by Canadians who cannot access regular dental care, including lower income families with no insurance, seniors in long-term care, new immigrants, and Indigenous peoples.<sup>2,13</sup>

Fluoride is a negative ion ( $F^-$ ) of the element fluorine ( $F_2$ ).<sup>14</sup> The term fluoride also refers to compounds containing  $F^-$ , such as sodium fluoride ( $NaF$ ), calcium fluoride ( $CaF_2$ ), fluorosilicic acid ( $H_2SiF_6$ ), or sodium fluorosilicate ( $Na_2SiF_6$ ).<sup>14</sup> In water, these compounds dissociate to release  $F^-$ .<sup>14</sup> Fluoride compounds exist in soil, air, plants, animals, and water.<sup>15</sup> Epidemiological studies in the 1930s and 1940s found that people living in areas with high naturally occurring fluoride levels in water had lower incidence of dental caries (i.e., cavities and tooth decay), a chronic and progressive disease of the mineralized and soft tissue of the teeth. This finding led to the controlled addition of fluoride to community drinking water with low fluoride levels in order to prevent dental caries.<sup>16,17</sup> In 1945, Brantford, Ontario, was the first city in Canada and the third city in the world to implement drinking water fluoridation.<sup>18,19</sup>

Fluoride helps to prevent dental caries both systemically (pre-eruptive or before the teeth emerge) and topically (post-eruptive or on the tooth surface).<sup>20,21</sup> The systemic effect occurs through the incorporation of ingested fluoride into enamel during tooth formation, which strengthens the teeth, making them more resistant to decay.<sup>21-23</sup> The major sources of systemic fluoride are fluoridated water and foods and beverages prepared in areas with fluoridated water.<sup>24,25</sup> Fluoride from other sources such as toothpaste, mouth rinses, gels, varnishes, or foams provides a topical effect (unless swallowed) through direct contact with exposed tooth surface; this increases tooth resistance to decay against bacterial acid attack by inhibiting tooth de-mineralization, facilitating tooth remineralization, and inhibiting the activity of bacteria in plaque.<sup>26</sup> As well, after being absorbed systemically, a small portion of fluoride is excreted into the saliva where it provides a topical effect from the continuous bathing of saliva over the teeth.<sup>27</sup> Evidence has suggested that CWF is associated with a decrease in dental caries, a decline in numbers of hospital attendances for general anesthesia and tooth extractions, and a reduction in the cost of dental treatment in children.<sup>28-34</sup>

Daily intake levels of fluoride in humans vary depending on many factors, these include sources of fluoride (water, foods or beverages, or dental products), levels of fluoride in water or foods, the amount of water or food consumed, and individual characteristics and habits.<sup>14</sup> About 75% to 90% of ingested fluoride is absorbed through the gastrointestinal tract, and up to 75% of the absorbed fluoride is deposited in calcified tissues (such as bones and teeth) in the form of fluorapatite within 24 hours.<sup>35,36</sup> The rest is excreted primarily in the urine, with

small amounts excreted in perspiration, saliva, breast milk, and feces.<sup>35,36</sup> In 2007, a dietary survey of the Canadian population estimated that the average intake of fluoride in children aged one to four years old in fluoridated and non-fluoridated communities was 0.026 mg/kg/day and 0.016 mg/kg/day, respectively.<sup>14</sup> The average dietary intake of fluoride in adults 20 years and older ranged from 0.038 mg/kg/day to 0.048 mg/kg/day in fluoridated communities, and ranged from 0.024 mg/kg/day to 0.033 mg/kg/day in non-fluoridated communities.<sup>14</sup> Based on the average daily dietary fluoride intakes in fluoridated areas (i.e., 0.7 to 1.1 ppm) in Canada and US, the recommended adequate intake (AI) of fluoride from all sources that is sufficient to prevent dental caries is 0.05 mg/kg/day, irrespective of age groups, sex, and pregnancy status.<sup>37,38</sup> The tolerable upper limit (UL) value for infants through children aged eight years is 0.10 mg/kg/day.<sup>37</sup> The UL for children older than eight years and for adults including pregnant women is 10 mg/day.<sup>37</sup>

According to the 2010 Health Canada *Guidelines for Drinking Water Quality*, the maximum acceptable concentration (MAC) of fluoride in drinking water is 1.5 ppm (parts per million or mg/L), while the optimal level of fluoride in drinking water is recommended to be 0.7 ppm (reduced from the previous range of 0.8 ppm to 1.0 ppm) for providing optimal dental health benefits and minimizing dental fluorosis.<sup>15</sup> MAC was determined with moderate dental fluorosis as the end point of concern.<sup>15</sup> Thus, community water fluoridation (CWF) in Canada is the process of controlling fluoride levels (by adding or removing fluoride) in the public water supply to reach the recommended optimal level of 0.7 ppm and to not exceed the maximum acceptable concentration of 1.5 ppm.<sup>15</sup> Most sources of drinking water in Canada have low levels of naturally occurring fluoride.<sup>15</sup> According to a Canadian survey conducted between 1984 and 1989, the average, provincial, naturally occurring fluoride levels in drinking water ranged from less than 0.05 ppm in British Columbia and Prince Edward Island, to 0.21 ppm in Yukon.<sup>15</sup> The provincial and territorial data on drinking water in 2005 provided by the Federal-Provincial-Territorial Committee on Drinking Water showed that the average fluoride concentrations in fluoridated drinking water across Canada ranged between 0.46 ppm and 1.1 ppm.<sup>15</sup> As of 2017, about 38.7% of Canadians were exposed to CWF for the protection of dental caries.<sup>39</sup> The decision to fluoridate drinking water is not regulated at the federal, provincial, or territorial levels, but rather the decision is made at the municipal level and is often taken by means of a community vote (i.e., by referendum or plebiscite).<sup>14</sup>

While public and dental health agencies and organizations, and about 60% of Canadians, view CWF as an effective and equitable means of improving and protecting the dental health of populations, there continues to be opposition, resistance, and skepticism about CWF, especially in terms of human and environmental health.<sup>40-42</sup> There are a variety of different perspectives on CWF, some of which centre on the scientific evidence of dental benefit,<sup>42,43</sup> while others include the availability of alternative oral public health programs or interventions that avoid perceived concerns of CWF.<sup>43,44</sup> Alternative publicly funded oral public health programs, such as school-based topical fluoride varnishes, though available, are not consistent across Canadian jurisdictions.<sup>45-47</sup> Importantly, the available programs are not universal in nature and mainly target high-risk populations.<sup>45,46</sup> Furthermore, public health programming is often targeted toward youth, excluding the adult and elderly populations. CWF, in contrast, is an intervention that reaches a broader population, so long as persons drink from municipal water supplies. Still, others cite potentially harmful side effects of fluoridation, for example, fluorosis, thyroid function, lowered average intelligence quotient (IQ) in populations, and negative environmental impact<sup>14,48</sup> as motivation for water fluoridation cessation. Additional concerns include possible relationships between industry and fluoridation.<sup>14,48</sup> Finally, an unsettled tension exists around the ethics of CWF in terms of

distribution of benefits to all persons who consume fluoridated tap water, removing (or making very difficult) the ability to “choose” fluoridation.<sup>43,49-51</sup>

It is within this context that some municipalities are choosing to cease water fluoridation, leading to its decline.<sup>39</sup> Notably, large Canadian cities such as Calgary, Quebec City, Windsor, Moncton, and Saint John have discontinued their water fluoridation programs in recent years.<sup>52-54</sup> Other municipalities have also discontinued CWF across provinces and territories since 2012.<sup>39</sup> Although the total percentage of Canadians with access to CWF has increased from 2012 (37.4%) to 2017 (38.7%), some provinces and territories have shown a significant decline in fluoridated water system coverage.<sup>39</sup> As of 2017, the provinces and territories with the fewest municipalities with CWF systems include British Columbia, Quebec, New Brunswick, Newfoundland and Labrador, and Yukon.<sup>39</sup> The impact of the CWF cessation on dental health is unclear.

## Policy Question

This Health Technology Assessment (HTA) is intended to provide guidance to policy- and decision-makers at the municipal levels to help orient discussions and decisions about water fluoridation in Canada. This HTA seeks to address the following policy question: Should community water fluoridation be encouraged and maintained in Canada? The analytic framework informing this HTA is presented in Appendix 1.

## Objectives

The aim of this HTA is to inform the above-mentioned policy question through an assessment of the effectiveness and safety,<sup>55</sup> economic considerations,<sup>56</sup> implementation issues,<sup>57</sup> environmental impact,<sup>58</sup> and ethical considerations<sup>59</sup> for CWF. An analysis of the evidence related to these considerations comprises different chapters of the HTA, each with specific and different research questions and methodologies. The following report presents the ethics analysis. Other sections have been published separately.

## Research Questions

The HTA addressed the following research questions:

### Review of Dental Caries and Other Health Outcomes

1. What is the effectiveness of community water fluoridation (fluoride level between 0.4 ppm and 1.5 ppm) compared with non-fluoridated drinking water (fluoride level < 0.4 ppm) in the prevention of dental caries in children and adults?
2. What are the effects of community water fluoridation cessation (fluoride level < 0.4 ppm) on dental caries in children and adults compared with continued community water fluoridation (fluoride level between 0.4 ppm and 1.5 ppm), the period before cessation of water fluoridation (fluoride level between 0.4 ppm and 1.5 ppm), or non-fluoridated communities (fluoride level < 0.4 ppm)?
3. What are the negative effects of community water fluoridation (at a given fluoride level) compared with non-fluoridated drinking water (fluoride level < 0.4 ppm) or fluoridation at different levels on human health outcomes?

### Economic Analysis

4. From a societal perspective, what is the budget impact of introducing water fluoridation in a Canadian municipality without an existing community water fluoridation program?

5. From a societal perspective, what is the budget impact of ceasing water fluoridation in a Canadian municipality that currently has a community water fluoridation program?

### **Implementation Issues**

6. What are the main challenges, considerations, and enablers related to implementing or maintaining community water fluoridation programs in Canada?
7. What are the main challenges, considerations, and enablers related to the cessation of community water fluoridation programs in Canada?

### **Environmental Assessment**

8. What are the potential environmental (toxicological) risks associated with community water fluoridation?

### **Ethical Considerations**

9. What are the major ethical issues raised by the implementation of community water fluoridation?
10. What are the major ethical issues raised by the cessation of community water fluoridation?
11. What are the major ethical issues raised by the legal, social, and cultural considerations to consider for implementation and cessation?

The ethics analysis addressed research questions 9 to 11.



## Background

Ethics is the inquiry into goodness or rightness in life; it examines questions about what we owe to each other and what it means to be a good person. Applied ethics uses ethical or moral theory (ethics and morals are used interchangeably in this analysis) to find answers to these questions for particular topics and contexts. Topics or questions in which important values are clearly at stake for individuals or populations are called ethical issues. An ethical issue may also be an ethical dilemma if two competing values are at stake. For example, whether or not to require health care providers to be vaccinated is an ethical issue because it challenges two important values: the value of supporting freedom and independence, and the value of patient safety and maximizing public health. Throughout this document, the word “patient” will be used as a general term to refer to people who will receive a particular intervention (including CWF). This is intended to simplify, and will stand in for other terms such as client, consumer, etc. It is also an ethical dilemma because it is not possible to live up to both values in their entirety at once. The goal of an applied ethics inquiry is to balance values and arrive at a resolution for the question at hand.

Ethics analysis is used in this report to evaluate health technologies for ethical issues and dilemmas. HTA is the evaluation of technologies to determine whether they should be implemented (and sometimes publicly funded). HTA is fundamentally value-laden and proceeds with the following implicit values:

- the technology should achieve the goal it is set out to achieve
- the technology should achieve that goal without creating more harm than good
- the financial requirement to adopt and implement the technology should not be disproportionate to its benefit
- adopting the technology should not pose serious threats to human integrity and dignity.

The purpose of this analysis is to identify and reflect upon key ethical concerns that should be considered when comparing the relative merits and demerits of CWF versus no CWF for the prevention of dental caries in children and adults in Canada. Although other sections of this HTA implicitly touch upon broadly ethical concerns, the aim of this analysis is to make such issues explicit and to identify others that may be relevant to any decisions in this regard.

## Inquiry

To answer the core question, ethics analysis requires a two-step approach to identifying potential issues. The first is a review of the ethics, clinical, and public health literature to identify existing ethical analyses of the technology. The second is a *de novo* ethical analysis based on gaps identified in the ethics literature and the results of concurrent reviews being conducted as part of the broader HTA. Through this approach, we identify and assess the relative importance and strength of the identified concerns and proposed solutions, identify and assess issues that have not yet come to the attention of ethics researchers, and delineate ethical desiderata for possible solutions to the issues where such solutions have not yet been proposed.

Insofar as this process involves concerns in applied ethics, typically the analysis will reflect on the specific details of community and individual perspectives, clinical effectiveness and safety, economic analysis, environmental impacts, and implementation considerations. As such, the ethical review involves an iterative process whereby the analysis is responsive to

results of other analyses conducted as part of this HTA, including the Review of Dental Caries and Other Health Outcomes, Implementation, Environmental, and Economic reviews.<sup>55-58</sup>

## Methods

A review of the empirical and normative bioethics literature was conducted to identify literature relevant to the identification and analysis of the potential ethical issues related to CWF.

The literature search was performed by an information specialist using a peer-reviewed search strategy.

Ethics-related information was identified by searching the following databases: MEDLINE (1946–) via Ovid, PsycINFO (1967–) via Ovid, CINAHL (1981–) via EBSCO, and PubMed. 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 fluoridation and fluoride in water.

Methodological filters were applied to limit retrieval to studies related to ethical, legal, and social issues. No date limit was applied. The search was limited to English- or French-language publications. Conference abstracts were excluded from all searches.

The initial searches were completed in November 2017. Regular alerts were established to update the searches until publication of the final report. Regular search updates were performed on databases that do not provide alert services.

Grey literature (literature that is not commercially published) was identified by searching the *Grey Matters* checklist (<https://www.cadth.ca/grey-matters>), which includes the websites of HTA agencies, clinical guideline repositories, systematic review repositories, and professional associations. Google and other Internet search engines were used to search for additional Web-based materials. These searches were supplemented by reviewing the bibliographies of key papers and through contacts with appropriate experts and industry.

The selection of relevant literature proceeded in two stages. In the first stage, the title and abstracts of citations were screened for relevance by a single reviewer. Articles were categorized as “retrieve” or “do not retrieve” according to the following criteria:

- provides normative analysis of an ethical issue arising in the use (or not) of CWF
- presents empirical research directly addressing an ethical issue arising in the use (or not) of CWF
- explicitly identifies, but does not analyze or investigate empirically, an ethical issue arising in the use (or not) of CWF.

The goal of this review of bioethics literature was to canvass what arises as an ethical issue from a broad range of relevant perspectives. As such, the quality of normative analysis does not figure in the article selection criteria: any identification of an issue by the public, dental care providers, researchers, or policy-makers is of interest, whether presented through rigorous ethical argumentation or not. For example, academic ethicists may focus on certain issues because they relate to theoretical trends in their discipline, while an opinion piece by a dental leader, policy leader, or member of the public may bring to the fore ethical questions that are neglected by academic ethicists but are highly pertinent to the assessment of the technology in the relevant context. Despite the different standards of

normative argumentation for each kind of report, the importance of the issues raised cannot be assessed solely by these standards; therefore, literature cannot be excluded based on methodological standards.

In the second stage, the full-text reports were reviewed by two reviewers. Reports meeting the above-mentioned criteria were included in the analysis; reports that did not were excluded. Disagreements between reviewers were resolved by discussion.

During the screening process, we also identified ethical issues from articles captured by the literature search that did not meet the strict relevance criterion of explicitly mentioning ethical issues. This second stage reflects the more typical approach ethics scholars take, which is to perform a comprehensive literature review to uncover relevant material, relying in part on reason and judgment. Although a formal systematic review is an excellent way to gather relevant articles within the scientific literature, ethics issues are often not named explicitly in articles, which can make identifying good search terms challenging. For example, an article may describe the inequities in access to dental care without ever being explicit about the clearly ethical dimensions relating to fairness and justice. This can create issues if the inclusion or exclusion criteria require that the article's subject matter be explicitly identified as about or relating to "ethics."

In addition, rigour in ethics scholarship comes from accurate contextualization and strong arguments, and unlike scientific findings, ethics conclusions do not become more significant as their frequency in the literature increases. Similarly, the lack of material about the ethics dimensions of a particular technology does not mean that there are no ethical issues raised by the technology. For these reasons, implicitly raised ethical issues identified by the reviewers were used to supplement the systematic review and achieve a robust ethics analysis by giving these issues equal weight.

## Results

The literature search yielded 1,271 unique citations. Four citations were added from the grey literature search, resulting in the review of 1,275 initial citations. Ultimately 112 full-text articles were included; 26 that explicitly discussed ethical issues in CWF, and 86 that provided implicit ethics discussions. See Appendix 2 for the flow diagram of the literature search and selection process.

The results of the Review of Dental Caries and Other Health Outcomes, Economic, Environmental, and Implementation reports<sup>55-58</sup> were also examined for information relevant to the ethics analysis. Appendix 3 provides a summary of the ethical issues that emerged from the literature.

## Analysis

### What Are the Ethical Implications of Community Water Fluoridation?

This section is organized by broad ethical themes, and outlines arguments for and against CWF as identified in the literature review. It draws from relevant evidence from either the ethics field or other sections of this HTA. This section is aimed at policy-makers and leaders to support their understanding of the different potential arguments and counter-arguments found in the literature.

Factual claims in this section (particularly to do with the health, safety, and environmental impacts of CWF) should not be taken as supported by the results of this HTA unless clearly indicated.

### *Respecting Individual Choice*

The duty to respect individual autonomy is a central tenet of health ethics, and, in particular, clinical ethics in many Western contexts. In clinical settings, this value is reflected in the informed consent processes, which requires that patients (or their surrogates) are provided with clear and accurate information about treatment options, as well as their associated risks, benefits, and potential outcomes. In public or population health contexts where various publics may be subject to the consequences of the presence or absence of a social feature (e.g., trans fats in food, cycling without helmets) the emphasis tends to be less on what the individual may think or prefer, and more on the overall impact of these consequences, and the extent to which they may contribute to or detract from the population's health.<sup>60</sup>

Various authors have argued that CWF is similar to public health interventions, such as chlorination of municipal water<sup>61-63</sup> and fortification of food stuffs,<sup>63-65</sup> and so should similarly be considered with less emphasis on consent and individual autonomy, and with a greater focus on the beneficial outcomes expected by the intervention. Nevertheless, the systematic review of ethics issues found significant concerns with the extent to which CWF limits individual choice, with several authors mounting the argument that consent should be required for CWF, and therefore ought not to proceed without it.<sup>50,51,66-73</sup> How one conceptualizes CWF can have significant implications for whether one thinks consent to CWF should be necessary. A number of authors argue that fluoride ought to be understood as a medication, and as with other medications, ought not to be provided without consent.<sup>66,68,74</sup> Some authors take this one step further to suggest that a meaningful informed consent process for medication requires that individuals who may ingest the medication be informed of the potential risks and benefits that the medication poses to them specifically. Given that individuals are generally not directly informed of the specific risks and benefits of CWF by qualified health professionals, they are not able to give the necessary informed consent, therefore, according to this argument, CWF cannot be ethically justified. Others argue that some of those who would consume fluoridated water do not have the capacity to give informed consent (due to age, cognitive capacity, etc.), and so would not be able to provide the necessary consent to CWF.<sup>73</sup> This is of particular relevance because CWF is believed to be particularly beneficial to children (for more detail, see the associated Review of Dental Caries and Other Health Outcomes report).

Drawing from a view that there is a lack of understanding about the long-term effects of CWF, some authors have proposed that CWF is an ongoing experiment or research activity. National policies (for example, in Canada, the Tri-Council Policy Statement) require that individuals give their consent to participate in research. Again, because there are no opportunities to provide consent to participate in this research, or to exclude oneself, the argument concludes that there isn't ethical justification for CWF.<sup>72</sup>

It is generally recognized that respecting individual autonomy is one of many important values, and that other values — for example, the duty to improve population health (discussed in greater detail later on in this report) — are also important. Some have acknowledged that while respecting individual choice is important, this can be overridden if doing so allows for an increase in the collective good, particularly if the intervention is minimally intrusive for the individual.<sup>63</sup> These authors note that the actual day-to-day burden

of CWF for individuals is very low, and does not create obvious limitations on individual liberty.<sup>63</sup>

For some authors, the reasoning goes the other way. Simply put, they argue that an intervention being safe and of benefit is not a sufficient criterion to make it ethically justifiable. They feel consent is also required.<sup>75</sup> Others point to alternatives to CWF that can expose individuals to fluoride (e.g., supplements, fluoride rinses), which allow for individuals to choose whether to make use of these methods. Because it would be possible to provide fluoride to the public in ways that do not override individual autonomy, the argument goes, it is not ethically justifiable to provide fluoride in a way that does not respect autonomy.<sup>51</sup> Some also note that it is very difficult and costly to avoid fluoride when one's municipal water supply's fluoride levels are adjusted. Doing so involves purchasing water from other sources, or the use of costly filtration systems,<sup>76</sup> both of which can be burdensome for those who do not wish to consume fluoride in their water. One might also argue that in communities without CWF it is similarly costly and burdensome to seek out resources for those desiring fluoridation.

The concept of autonomy or freedom of choice in the context of CWF also arises when considering a parent's role in providing for their children's health. Some scholars have argued that a positive feature of CWF is that it can reach vulnerable persons, in particular children, who may especially be able to benefit from exposure to fluoride without depending on the actions of others.<sup>62,63,65</sup> This notion of vulnerability will be discussed in more detail in a later section of this report. It is worth noting, however, some concerns raised by scholars about whether CWF entails a usurpation of parental rights in favour of decisions made by the state.<sup>61</sup> Irrespective of their children's vulnerability, parents are generally given broad authority to determine how best to promote their children's health and well-being. This would generally extend to what substances their children ingest. There is a general social consensus, at least in Western contexts, that it is not appropriate for the state to seek to promote the health of children in a way that infringes on parental liberties.<sup>62</sup> One could argue that CWF entails disproportionate infringements on parent authority, and therefore ought not be provided.<sup>61</sup>

Other commentators have offered a response to this argument, suggesting that CWF reaches children directly with very little infringement on parental liberties (e.g., it does not require parents to buy special equipment, to submit to particular health care visits) so is not a disproportionate infringement on parental authority.<sup>62</sup> Some authors have allowed that it may be an infringement on parental authority but have explored the extent to which this may be justified. First, there are many ways in which the state limits and imposes on parental decision-making (for example, with rules requiring seat belts, mandatory air bags in cars, the provision of education to children, etc.) and so CWF is no different than these circumstances. Further, as one author argues,<sup>61</sup> the parental rights to preserve and promote their children's health arise from their duties to do so. This is duty because children have a right to health and the medical services necessary to achieve health. This author proposes that the children's right to health is more basic and fundamental than the parent's right to provide health, so if circumstances arise where a child's health is compromised as a result of parental choices, there is ethical justification for the state to step in. This, the author proposes, justifies CWF over relying on parental decision-making to provide fluoride to their children.<sup>61</sup>

Some scholars have pointed out that CWF may also be perceived to restrict the right of religious liberty.<sup>61</sup> Christian Scientists, in particular, believe that those who are ill are made

well with mental and spiritual influences, and not by means of medication. This group is not in favour of CWF; while they do not wish to impose their beliefs on others, they also believe that what they take to be medical treatment shouldn't be imposed on them.<sup>61</sup> Those who have responded to this argument make a distinction between freedom of religious belief and freedom of profession and practice. The former is an absolute right, whereas the latter may be restricted if concerns for the greater good require it.<sup>61</sup> This line of argumentation suggests that CWF can be justified for reasons of promoting the greater good, even if this curtails the religious profession and practice of others.

The Principle of Least Infringement balances the interests of individuals to avoid restriction on choice with the anticipated benefits of desired interventions.<sup>62</sup> It proposes that the least restrictive or invasive option to achieve the beneficial outcomes ought to be pursued. In other words, if the same goal can be achieved with a less intrusive approach than with a more intrusive one, the less intrusive approach shall be taken. This principle attempts to balance values of autonomy and choice (discussed previously) with those of optimizing population health and well-being.

Similar to some of the previously mentioned arguments, some commentators on CWF argue that it does not align with the Principle of Least Infringement because there are other alternatives (e.g., supplements, rinses, etc.) that could achieve the same effect while also being less restrictive on individual choice.<sup>66,77</sup> Of note, there may be varying judgments around how notions of infringement and intrusiveness are interpreted. Within the debate around CWF, water fluoridation is generally taken to be intrusive or an infringement because it is provided without seeking the consent of the recipient, which limits choice. One might argue that CWF is less intrusive than its alternatives because it does not require any additional action or lifestyle change (e.g., the purchase and use of supplements). If we accept that CWF is more intrusive than alternative sources of fluoride, the strength of the argument that CWF does not live up to the Principle of Least Infringement depends on whether the alternatives truly can achieve the same effect. Some studies on alternative sources of fluoridation suggest that they are not as effective or cost-effective as CWF,<sup>78,79</sup> though a full exploration of alternative methods of fluoridation is outside the scope of this HTA. As a result, it is not possible to evaluate whether CWF aligns with the Principle of Least Infringement.

### **Implications for This Health Technology Assessment**

It would be impracticable to provide CWF with consent, so current and future CWF programs will likely continue to face the criticism that they are insufficiently respectful of individual choice. Conceptualizing CWF as a public health intervention (rather than a medical treatment) invokes an ethical framing that gives greater priority to duties of benefit (discussed later in this report), which supports arguments that interventions that limit individual choice can be justified if they sufficiently promote population benefits, especially if the individual burdens that may arise as a result are minimal. Such arguments are provided to support seat belt laws, air bags in cars, vaccination programs, and public health education campaigns.

Some authors have argued that with other public health interventions individuals still have the option to opt out (e.g., to choose simply not to wear the seatbelt, granting that this could have legal consequences) whereas it is comparatively more difficult to opt out of fluoride that is added to water that goes directly in to the home. For this reason, they argue, CWF cannot be justified as other public health interventions can be, because the comparative restrictions on choice with CWF are much higher. Whether other public health interventions can simply

be avoided is a matter of some debate (e.g., it would be difficult to “unsee” a public health message on a billboard, and some countries are considering fining parents who do not vaccinate their children), nevertheless the fact that CWF is provided in water without individual consent is a matter of fact. This does not necessarily mean that CWF cannot be ethically justified (see Discussion section for more detail); it will be important for policy-makers and leaders to be aware of this issue and how it may arise in their own organizations and jurisdictions.

### *Maximizing Benefits and Minimizing Burdens for Populations*

The value or principle of maximizing benefits and minimizing burden for populations outlines the duties of those organizing and delivering health-related interventions to populations to maximize opportunities for broad benefit in the population and minimize risks and exposures of harms as a result of these interventions. Generally, public funding for interventions is intended to improve the health and well-being of a population; however, the specific intentions and goals of services, as well as the effectiveness of interventions, need to be considered when assessing benefit at the population level.

The intention of CWF programs is to improve oral health by providing fluoride to the population through consumption of municipal drinking water. The Review of Dental Caries and Other Health Outcomes<sup>55</sup> of this HTA outlines population effects of CWF as has been determined through the review of the evidence. These findings will be discussed later in this section.

The systematic review of the ethics literature uncovered divergent views regarding the extent to which CWF fulfills the duties to maximize benefit and minimize harms to populations, generally due to differing perspectives on the content and rigour of the scientific evidence. Discussions of CWF often start with the observation that oral health is an important component to general health, and a lack of oral health can reduce quality of life due to experiences of pain, discomfort, and decreased function.<sup>63</sup> Some authors accept the evidence that indicates that CWF reduces the incidence of caries and argue that fewer caries means better oral health, therefore CWF does fulfill duties to benefit the public.<sup>51,61,66</sup> Others acknowledge that CWF can cause fluorosis (results in the Review of Dental Caries and Other Health Outcomes indicate a 40% prevalence of fluorosis at 0.7 ppm) but suggest that this is a primarily cosmetic issue and therefore not sufficiently problematic to limit CWF.<sup>55,63,66,77</sup> Other authors have suggested that CWF also leads to reduced rates of hip fracture, and therefore offers even greater benefits than simply those to oral health,<sup>63</sup> though the Review of Dental Caries and Other Health Outcomes did not note any association with reductions of hip fractures due to fluoridation.<sup>55</sup>

Other authors are more agnostic about the evidence of positive health outcomes for CWF, suggesting that there isn't yet sufficient evidence to know the full impacts of CWF for both humans and the environment<sup>51,66,68</sup> (though the environmental assessment of this HTA suggests the environmental impact from fluoridation would be minimal). Some authors offer the conditional perspective that *if* CWF involves no significant risk to life or health, then it may be added with the intention to improve dental health,<sup>61,62,73</sup> without committing to whether there is sufficient evidence for benefit. Finally, some authors argue that CWF is harmful to populations because it creates toxic effects, dental and skeletal fluorosis, bone fractures, and hypersensitivity reactions,<sup>68,80</sup> which suggests that it would not fulfill duties to create benefit and avoid harm.



### **Cosmetic Appearance**

In terms of non-health outcomes, some commentators argue that dental appearance can have significant social impacts, particularly on earnings and employment opportunities.<sup>63</sup> They argue that generally, fluorosis caused by water fluoridation has a negative impact on the appearance of the teeth. In light of these impacts, the aesthetic consequences of water fluoridation, they argue, should be considered more carefully because it would not be appropriate to dismiss these as superficial or irrelevant. Typically, these commentators do not acknowledge the potential cosmetic improvements offered by CWF through its effect at reducing tooth decay, cavities, and extractions, which may also impact appearance. Recent studies on oral health have indicated that the prevalence of moderate fluorosis — the level at which fluorosis may start to be an aesthetic concern — is so low that it barely reaches a reporting threshold.<sup>2</sup>

### **Fluoride as a Potential Poison**

Some of these concerns regarding harm arise from a basic concern about the safety of the substances used to fluoridate water. Some authors have argued that fluorosilicic acid (one of the sources of fluoride used in CWF) can be contaminated by lead, arsenic, and mercury; therefore, no safe level of fluoride from this source is possible.<sup>66,70</sup> Others have raised concerns that in light of these contaminants, those who monitor fluoride at water treatment plants are not sufficiently qualified to monitor the safety of fluoride, thus increasing the perceived risks of harm by CWF.<sup>70</sup> With the observation that the dosing of fluoride through CWF can vary significantly with individual characteristics and consumption of tap water, some authors have raised concerns that this lack of control over dosage may also create issues with safety,<sup>74</sup> in addition to the lack of professional oversight on the impacts of CWF on individuals, which may vary further with individual sensitivities.<sup>71</sup>

### **The Precautionary Principle**

Some authors who remain uncertain about the health consequences of fluoride invoke the Precautionary Principle, arguing that without clear evidence of benefit and the potential that CWF may be harmful, it would be most ethically defensible to reduce fluoride intake (including intake through CWF programs).<sup>66,70,77</sup> One could respond to this position by pointing out that there is evidence for the benefit of CWF (as is reported through the Health Outcomes review of this HTA);<sup>55</sup> however, those who invoke the Precautionary Principle may do so because they may not trust the existing scientific evidence, or may not believe that it has not sufficiently explored the long-term effects of CWF.

### **Necessary Expertise**

A number of authors question whether medical experts would have the expertise necessary to assess the full scope of benefit that would be necessary to truly determine if CWF is beneficial to populations.<sup>50,80,81</sup> These arguments suggest that medical experts (and, presumably, health researchers) would have the expertise to identify the potential health-related outcomes of CWF, but would not have the skills or expertise to evaluate other factors included in benefit, including whether the program aligns with recipients' beliefs about what benefit means to them, for example. This line of argument raises general questions about what information might be necessary to make decisions in the public's interest and would not be specific to CWF.



### **Alternative Means of Providing Fluoride**

In considering the potential benefits and harms of water fluoridation, some authors have questioned whether such programs are necessary, especially given the other ways fluoride can be delivered (toothpaste, mouth rinses, fluoridated milk and salt, etc.) They suggest that fluoride in water is not necessary, given these other vehicles.<sup>66</sup> In response to the argument that these alternative means of providing fluoride may not be accessible to all members of the community (due to finances, awareness of their benefits, access to professionals who may provide these materials) these authors argue that subsidies (for fluoride toothpastes, for example) and education could ensure broad uptake.<sup>66</sup> Others point to research that indicates that rates of tooth decay in Europe (where water is not generally fluoridated) are declining at similar rates to those in North America to suggest that factors other than CWF may be responsible for decreasing dental cavities, and that the benefits of water fluoridation may be overstated.<sup>72</sup> The Health Outcomes review was not designed to retrieve or assess the validity of such studies, so it is not possible to evaluate the claims made by the authors summarized here. There is some question about whether these alternatives are truly comparable alternatives with CWF. For example, fluoridated salt and milk are not widely available in Canada, and some individuals are not able to consume either due to health concerns (e.g., lactose intolerance and hypertension),<sup>14</sup> and fluoride rinses are not recommended for children under the age of six.<sup>82</sup>

### **Characterizations of CWF: Medicine, Research, Poison, or Fortification**

The descriptors and comparisons used in discussions of water fluoridation can reveal an author's assumptions or beliefs about CWF and may have an (often unacknowledged) impact on the reader's impressions of CWF as an intervention. Further, these conceptualizations can lead to inferences or conclusions about the regulatory responses to CWF that an author may suggest are required. It is beyond the scope of this review to conduct an extensive linguistic analysis of the literature on water fluoridation. The following discussion is included to demonstrate, first, that there are various conceptual framings of fluoridation in the literature, and, second, to show how these framings can lead to explicit or implicit judgments about the ethical status and permissibility of CWF, particularly with regard to whether it is seen as harmful or beneficial.

Some authors have suggested that fluoride (either the chemicals used to fluoridate or the fluoridated water itself) is best understood as a medicine because it is ingested and creates a physiological effect in the body.<sup>68,70,83</sup> If fluoride is a medicine, then CWF would be considered "mass medication."<sup>71</sup> If fluoridated water (or the materials used to fluoridate water) were considered a medicine, then the argument is that the usual processes of informed consent would be required prior to administering water fluoridation (see previous discussion on Respect for Autonomy). One could respond to this argument by pointing out that there are numerous other substances that are ingested that have a physiological effect that are not generally considered to be medicines, such as the other minerals found in tap water, including copper, sodium, and zinc.

Conceptualizing fluoride as a medicine can have further implications for regulation. Those who propose we understand that fluoride is a medicine argue that regulatory procedures for medicines and drugs ought to be followed, though one author (who has examined this issue extensively) has noted that such procedures, in countries where CWF exists, have not been consistently followed. For example, in the US and the UK, fluoridated toothpastes and other vehicles that deliver fluoride (e.g., tablets and rinses) are regulated as drugs or medicines, but some fluoridating chemicals (e.g., fluorosilicic acid) are not.<sup>68,70,83</sup> There is also the claim

that if the standards and rigours of drug regulation were applied to fluoride, it would be immediately removed from use because of the significant evidence of adverse effects (though readers should note that the Health Outcomes review of this HTA did not find evidence that CWF actually causes significant adverse effects).<sup>70</sup> Others reject the framing of fluoride as a form of medicine because, they argue, water fluoridation prevents, rather than treats, disease (though it is worth noting that many other interventions that are also preventive — e.g., statins and antihypertensives — are widely accepted as medicine).<sup>80</sup>

Another argument for increased oversight and limited access to CWF arises with the framing that there is still insufficient evidence about the potential impacts of water fluoridation; therefore, CWF should be understood as research.<sup>70,72</sup> Understood as research CWF would be subject to existing regulations of research oversight and the tenets of research ethics. Similar to arguments for the need for consent to medicine, if CWF is considered research, then participants (in this case, those receiving fluoridated water) would need to provide consent to participate in this research and would also need to be able to exclude themselves from the research exposure (water fluoridation) should they choose not to consent.<sup>70</sup>

Another framing that is sometimes presented by those with concerns regarding water fluoridation is that of fluoride as poison.<sup>68,70</sup> As evidence of this position, one author points out that sodium fluorosilicate, one of the substances authorized for water fluoridation, was (and may still be) recognized as a scheduled poison under the Poisons Act of 1972.<sup>68</sup> Others point out that silicofluorides used in water fluoridation are a by-product of the fertilizer industry and are best described as highly toxic hazardous waste.<sup>70</sup> It is worth pointing out that the fact that something is a by-product does not mean it is necessary “waste” or harmful. Further, materials that may be hazardous in one context or dose may not necessarily be hazardous in another. Nevertheless, those who oppose CWF have shown concern with these materials and choose strong language (like “toxic” and “hazardous”) to reflect these concerns.

Authors who tend to see water fluoridation more favourably have used other conceptual framings for fluoride. Some have argued that fluoride is equivalent to food fortification, such as the addition of iron to wheat flour.<sup>63-65</sup> Others have proposed that fluoride is more akin to a nutrient or natural trace element, which is essential to the body’s nutrition.<sup>80,84</sup> Fluoride has also been compared with chlorine, which is also added to water,<sup>61-63,65</sup> under the argument that chlorine and fluoride both serve to protect the body from disease. One response to this argument is that chlorine and fluoride are not equivalent because chlorine serves to treat the water, whereas fluoride treats the person.<sup>71</sup>

### **Implications for This Health Technology Assessment**

The review of the health outcomes evidence for this HTA (as reported in the Review of Dental Caries and Other Health Outcomes) has found that there is consistent evidence for an association between water fluoridation and a reduction in decayed, missing, and filled deciduous teeth (dmft) in children; a reduction in decayed, missing, and filled deciduous tooth surfaces (dmfs) in children; a reduction in caries prevalence and an increase in the proportion of caries-free deciduous teeth in children; a reduction in caries in permanent teeth (measured using DMFS and DMFT) in both children and adults; and a reduction in caries prevalence and increase in the proportion of caries-free permanent teeth in children and adolescents.<sup>55</sup> This (in addition to other outcomes for dental health reported in the Review of Dental Caries and Other Health Outcomes) suggests that there is sufficient evidence to show that CWF leads to improved oral health outcomes, and so seems to align with broad duties to promote benefit in populations.

The benefits of CWF for oral health are only one part of the equation. As previously discussed, some authors raise concerns about the potential physiological harms of water fluoridation. The benefits to oral health of CWF may not be sufficient to continue or implement CWF if it creates other harmful physiological outcomes (as some authors previously discussed have proposed). The Review of Dental Caries and Other Health Outcomes looked at 22 additional potential outcomes to determine whether CWF may adversely affect health.<sup>55</sup> For bone cancer, total cancer incidence and cancer-related mortality and hip fracture, there was consistent evidence of no association between these conditions and CWF. For Down syndrome and cognitive function, there was limited evidence for no association. For all remaining potential non-dental outcomes, there was insufficient evidence to determine the association between CWF and these outcomes (see the Review of Dental Caries and Other Health Outcomes for more detail).

The Review of Dental Caries and Other Health Outcomes did find consistent evidence for an association between an increase in the level of fluoride in drinking water and an increase in the prevalence of dental fluorosis.<sup>55</sup> Drawn from the results of the 2016 National Health and Medical Research Council review,<sup>85</sup> at 0.7 ppm there was a 40% prevalence of dental fluorosis (at any level). The prevalence of dental fluorosis of aesthetic concern was 12.0% and 12.5% at 0.7 ppm and 1.0 ppm, respectively.

It is worth responding to the concerns regarding the necessity of CWF in light of the availability of other modes of providing fluoride to populations discussed previously. As expressed at the beginning of the Review of Dental Caries and Other Health Outcomes, this HTA was conducted with the assumption that with the widespread use of fluoridated toothpaste in both fluoridated and non-fluoridated communities, the effect of fluoridation was considered to be above and beyond the effect of the fluoridated toothpaste and other common modes of fluoride provision. This suggests that while these modes that are simultaneously used in communities with CWF may have positive effects, CWF is necessary to see the magnitude of effects reflected in the literature (keeping in mind that this does not include other fluoride provision programs, like fluoridated salt and milk, which are not generally available in the communities under study). This raises questions about the potential consequences of CWF cessation. The Review of Dental Caries and Other Health Outcomes examines the data on cessation, though was unable to draw strong conclusions due to generally insufficient data.<sup>55</sup> More evidence will be needed to assess the necessity of CWF based on the impacts of CWF cessation.

The Principle of Proportionality indicates that an intervention can only be justified if its benefits are proportionate to the expected burdens. If CWF would involve significant danger to life or health (short or long term, to any individual or groups), it would be ethically unjustified, even if it did offer some benefit to other health in the population.<sup>61</sup> Some commentators on CWF have argued that the benefits of CWF are not proportional to its harms because they see the benefits of CWF as modest, and anticipate other harmful outcomes (e.g., dental fluorosis, higher risks of bone fractures and hypothyroidism<sup>66</sup>). Once again, this assessment depends on one's knowledge and trust of the relevant scientific literature. The arguments from Proportionality identified in this Ethics review (using the evidence and context discussed in this HTA) suggest that CWF offers proportional benefits over harms, and thus lives up to the Principle of Proportionality.

Overall, the findings from the Review of Dental Caries and Other Health Outcomes suggest that there is strong evidence of benefit of CWF and little evidence to suggest that it leads to other negative health outcomes, aside from dental fluorosis, though there is little research

on these other outcomes (e.g., bone cancer, etc.) that is relevant to the Canadian context.<sup>55</sup> These data suggest, therefore, that CWF does live up to our duties to promote benefit and minimize harms to populations. This conclusion is tempered somewhat by individual perspectives on what to do where there is insufficient evidence, particularly when it comes to other harmful outcomes. The Review of Dental Caries and Other Health Outcomes showed that there is no strong evidence of harm (as some authors have claimed) but was also not able to demonstrate that there was no association with these harmful consequences.<sup>55</sup> This lack of evidence regarding harms one way or another may create difficulty for some interpreting the Principle of Proportionality in this case.

The ethics analysis of this HTA responded to the evidence as it was gathered and presented in other sections with the assumption that this evidence is trustworthy, complete, and robust. Others involved in considering CWF may not share this assumption, and instead may approach the literature with more skepticism. Some authors have argued that scientific evidence about the potential harms of CWF has been systematically suppressed.<sup>80</sup> Others have questions about the science that is published, especially with respect to any influence industry and other interested parties may have had in the conduct of scientific research in this topic. A skepticism toward the science of CWF means that it is unlikely that more science, or more education about science, will lead to changes of opinion among some who do not support CWF. Even those who accept the evidence in the literature (and presented here) may feel that the fact that CWF creates population oral health benefit with few documented harms isn't enough to conclude that CWF is ethically permissible, as some may argue that these benefits are not sufficient to offset the infringement on choice and autonomy presented by CWF (as discussed in the previous section).

### *Equity and Justice: Distributing Benefits and Burdens Fairly*

The value of promoting equity (sometimes also thought of in terms of justice) is generally concerned with the fair distribution of benefits and burdens of resources. Normatively, it describes the duty to ensure that these are distributed with equal consideration for all, with the goal of ensuring that individuals have opportunities to access resources and to benefit from them.

It is well documented in the literature that there is inequity in oral health in Canada, across various demographic lines, and in particular, between socio-economic classes.<sup>63</sup> This is reinforced in part by the fact that most dental care is not covered under public health systems. Instead, access is determined through private insurance or direct payment from individuals. This results in dental care been distributed according to capacity to pay rather than according to need.<sup>73</sup>

Equity can be defined as the fair distribution of opportunities for outcomes across social groups;<sup>76</sup> this is distinct from equality, which is the equal allocation of resources across groups. Some authors have argued that CWF promotes equity because it minimizes caries among those who lack resources to seek dental care<sup>66</sup> and has been shown to reduce overall oral health disparities in communities.<sup>78</sup> Others argue that CWF is desirable because it promotes equality (where the same resources are provided to all) because everyone, regardless of class or other demographic, can benefit.<sup>50,51,86</sup> Furthermore, by virtue of its delivery in municipal water supplies, CWF ceases to be a discretionary commodity that is only available to those who are familiar with its benefits and can afford to buy it.<sup>51</sup> Some point out that CWF's passive mode of delivery gives it an advantage over toothpaste and other vehicles for delivering fluoride, which require intention and action to bring into the household.<sup>63</sup>

Not every author who writes about equity and CWF believes there is a positive association. Some authors are more cautious about whether CWF promotes equity,<sup>62</sup> whereas others argue that there is no evidence to suggest that CWF actually promotes equity.<sup>66</sup> Some authors propose that CWF actually perpetuates inequity because its perceived harmful effects will disproportionately affect the already disadvantaged.<sup>66,83</sup> Some commentators have proposed that those who are likely to benefit from CWF (those of a lower socio-economic status who have limited access to fluoride) are not the same individuals who may be harmed (such as infants, those with fluoride allergy, people with chronic renal disease; see the Health Outcomes Review<sup>55</sup> for a detailed discussion about whether there is evidence for these harms), raising questions about the appropriate distribution of burdens and benefits.<sup>50,66,67</sup>

Within the Canadian context, particular attention has been paid to health disparities between Indigenous and non-Indigenous populations, including disparities in oral health. Among Canadian Indigenous communities, there is a high prevalence of early childhood caries and their resulting adverse health effects, as well as high rates and costs of restorative dental interventions (including surgery under general anaesthesia<sup>87</sup>). CWF has been identified as a possible preventive measure of early childhood caries in Indigenous populations, though a 1998 survey indicated that less than 10% of First Nations people had access to fluoridated water compared with 45% of Canadians in general.<sup>87</sup> These disparities are clearly an equity issue, which CWF could, to an extent, address. Though a general call for CWF within Indigenous communities may come across as tone deaf, given that many communities struggle to establish a safe, clean source of drinking water at all, never mind worrying about how this water could eventually assist with oral health.

CWF occurs within existing municipal water supplies so questions of equity also arise with the consideration of rural (versus urban) populations. Individuals in smaller communities or who rely on well water (both of which tend to be within a rural context) are likely to have less access to CWF than their urban counterparts. See the Implementation review for more detailed discussion of this point.<sup>57</sup>

### *Protecting the Vulnerable*

Related to equity concerns, the value of protecting the vulnerable acknowledges that some populations or communities are more likely to have their interests overlooked or may be less able to advocate for their own needs. This requires that those who distribute resources and opportunities acknowledge and address such circumstances.

In discussions about water fluoridation, children, older adults, and others who may be at greater risk for poor oral health, and who may be less able to understand or advocate for their own needs are identified as particularly vulnerable. The ways in which CWF may affect vulnerability depends on one's view on the possible outcomes of CWF. Some individuals argue that we ought not to use CWF because we do not yet know its full outcomes, which would be felt more acutely by vulnerable groups such as children.<sup>66</sup> Others argue that CWF is protective for vulnerable populations because it offers benefits without relying on individuals to actively seek out such benefits.<sup>50</sup>

Children are often discussed in the CWF literature as they are simultaneously identified as vulnerable<sup>63,76,78,84</sup> and the group that could experience the greatest benefit from CWF (see results in the Review of Dental Caries and Other Health Outcomes).<sup>55</sup> Some have argued that this vulnerability creates greater cause to pay attention to the impacts of CWF on children, particularly small infants. Some authors have argued that infants consume a

disproportionate volume of fluids compared with adults in relation to their size, which could lead to several fold higher doses of fluoride (again, compared with adults), suggesting that greater attention to the impacts of fluoride on infants is necessary.<sup>84</sup>

Others start with the concern that children are vulnerable with regard to their oral health because they rely on the knowledge and behaviour of others (usually parents) and are generally not in a position to make informed choices about their own dental health.<sup>62</sup> Other modes of fluoride provision (such as fluoridated milk, salt, and toothpaste) have advantages because they offer choice to adults, but they have the disadvantage of reaching fewer kids in light of this choice.<sup>63</sup> CWF better protects children, it is argued, because it does not rely on the choices of the adults in children's lives to enable access to the benefits of fluoridation.<sup>62</sup> Some go so far as to argue that the vulnerability of children justifies overriding personal freedoms that come from choice; we can respect the freedom of choice of an adult eating sugary foods and not brushing their teeth, but this ceases to become a freedom when children are encouraged (explicitly or implicitly) to do the same.<sup>65</sup>

### *Community Water Fluoridation Costs*

Considerations of justice and equity arise with the examination of costs of a particular technology. It is appropriate to consider who bears the cost, how these burdens are distributed, and whether such costs limit access to others resources or goods. See the Economics report for a detailed analysis on the costs and budget impacts of CWF.

Some authors argue that CWF will lead to decreased public costs over time due to the overall reduction in caries.<sup>66</sup> Others see it as a matter of public stewardship that decisions be made (such as to engage in CWF) that result in needing fewer resources in the future (e.g., to treat caries in children<sup>81</sup>). This argument anticipates that CWF will lead to a reduced need for health resources because it will minimize the need for restorative dental treatment and infections (especially those requiring hospitalization and other medical treatment) that can be caused by caries.<sup>51</sup> Other authors worry about a direct effect on access to dental care if those who have preventable caries require time in the dentist's chair to "mend the error of their ways."<sup>65</sup>

Other authors argue that the benefits (in terms of costs) of CWF are overstated and that when one considers the maintenance and replacement costs of CWF it does not sufficiently offset any cost savings that CWF may accrue.<sup>66</sup> In particular, some authors note that any cost savings of CWF could be offset by the costs of fluorosis, which may require restorative dental treatment to address.<sup>65</sup>

Whatever the figures, it is noted that the overall health utilization costs of dental care are especially relevant in the case of CWF, as most oral health care services are not included in publicly funded health care schemes and are thus borne directly by the individual or through private insurance companies.<sup>51</sup>



### Implications for This Health Technology Assessment

The results of the systematic review of the ethics literature discussed previously raise several issues that can be examined in light of the empirical findings of both the Review of Dental Caries and Other Health Outcomes and the Economic analysis.<sup>56</sup>

In examining the impact of CWF (Question 1), the Review of Dental Caries and Other Health Outcomes found insufficient evidence to conclude that there is an association between water fluoridation and a reduction in the disparity in dental caries in deciduous and permanent teeth by socio-economic status. Further, there was limited evidence for no association between water fluoridation and a reduction in the disparity in dental caries experienced in deciduous and permanent teeth by Indigenous status. There was, however, limited evidence for an association between water fluoridation and a reduction in the disparity in dental caries experience in deciduous and permanent teeth and hospital admissions for caries-related dental extraction by levels of deprivation. When looking at the potential disparities that may arise from cessation of CWF (Question 2), the Review of Dental Caries and Other Health Outcomes found limited evidence for no association between CWF cessation and change in disparities in dental caries in children by levels of deprivation.

While individual studies have shown decreased inequities in communities with CWF compared with those without,<sup>78</sup> the data gathered through the Review of Dental Caries and Other Health Outcomes suggest inconclusive and mixed results regarding whether CWF has a measurable effect on equity.<sup>55</sup> Children of lower socio-economic groups experience higher incidences of dental caries than those of higher socio-economic groups, regardless of the presence of absence of CWF.

These findings do not mean that CWF does not offer benefit (the Review of Dental Caries and Other Health Outcomes found that it does) but rather, it shows that individuals benefit roughly equally (rather than those who are worse off benefiting more than those who are better off). This overall benefit raises questions about justice when it comes to the distribution of CWF across the country. Proponents have argued that CWF is non-discriminatory and beneficial; however, this is only true within populations served by a fluoridated municipal water supply. The Implementation review indicates that only 37% of Canadians have access to CWF, which, if it is truly beneficial, leaves a significant proportion of individuals who do not have access to this benefit (not to mention the proportion of Canadians who do not have access to safe drinking water at all).<sup>13,57</sup>

This sporadic distribution of CWF also maps along other demographic lines, including between urban and rural populations, and among urban populations, according to wealth. Larger, wealthier cities tend to have CWF programs (with a few exceptions), whereas smaller, less well-off cities do not (see the Implementation review for more details).<sup>57</sup> All of these factors point to larger questions of equality in access to CWF. The ethical challenges arise, therefore, not with the absence of impact on equity between CWF and non-CWF communities, but with overall inequalities in access to programs shown to be beneficial for oral health.

With regard to the distribution of burden of costs, the results of the Ethics review suggested that oral health costs are generally borne by private individuals, indicating that they would be the beneficiaries in any reduction in costs with the implementation of CWF, as well as the bearers of additional costs should CWF be discontinued (or never implemented). This was confirmed in the Economic Analysis, which found that the primary investors in CWF (unless

subsidized by provincial funders, as in Quebec) are the municipalities, whereas the primary beneficiaries seem to be private (including private insurance and out-of-pocket customers) and, to a lesser extent, provincial, territorial, and federal governments.<sup>56</sup>

This HTA did not find that CWF promoted equity (i.e., a reduction of oral health disparity) to the extent that some studies have found.<sup>78,79</sup> Nevertheless, municipal CWF programs fulfill some dimensions of equity because among the households connected to the system, every tap has access to the fluoride adjustment, regardless of the demographics of those in the home.

### *Duties of the State*

For some, the differing perspectives about the ethical permissibility of CWF arise with foundational views about what is the appropriate role of the state in promoting individual and population health. In nations like Canada,<sup>51</sup> it is generally accepted that the state (usually national, provincial, and municipal governments) has some role in preserving and promoting the public good, though perspectives about how this should be done vary. Within the context of CWF, some of the differing views about its permissibility arise with divergent perspectives on the appropriate role of government and, in particular, the extent to which governments can be permitted to limit individual choice and liberty. This question may be particularly complex within the context of oral health as it is less clear who, be it the state, the private sector, or the individual is (or ought to be) responsible for teeth.<sup>81</sup> And, as with many aspects of the debate on CWF, perspectives are also heavily informed by beliefs about the health impacts (positive and negative) of adjusting fluoride in water sources.

Several articles retrieved in the Ethics review argue that it is the duty of the state to secure the common good of citizens, and that water fluoridation is consistent with this duty, even if it means that CWF restricts the rights of those who do not wish to have fluoride in their tap water.<sup>61,73,84</sup> This is especially true if there is no other suitable, practicable, and effective means to achieve the goals of CWF, though some caution that overriding autonomy can only be justified if there is evidence of benefit of the good consequence.<sup>62,67</sup>

A number of other authors propose that while governments may have a role in promoting the good for its citizens, the state ought not to override individual autonomy to improve oral health.<sup>61,68,75,83</sup> Some authors present the view that it may be appropriate for the state to limit individual choice when the health impacts of not doing so would be serious, but argue that tooth decay does not qualify as a serious health threat, so the usurping of individual rights is not justified.<sup>70</sup> Whether or not tooth decay is a serious health threat is a matter of debate, of course. Recent media reports have suggested that dental care under anesthesia is risky for children<sup>88,89</sup> and further, that oral disease is connected to other serious health issues like cardiovascular disease.<sup>90</sup>

Echoing the discussions earlier in this section about fluoride as medication, some authors propose that health interventions in the name of public health, which involve intervention at a personal level (which they propose fluoridation is), bring public health into the realm of medical practice. This puts public health interventions like water fluoridation in tension with the regulatory and ethical frameworks that guide clinical practice, and so, could put the state in conflict with professional roles in health care.<sup>83</sup> It has also been pointed out that some state's commitments seem to conflict with CWF; for example, one author said that Article 2 of the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine indicates that an individual's choice with respect to their treatment for medical conditions takes precedent



over state objectives,<sup>70</sup> suggesting that this convention ought to be respected and CWF not provided.

Several authors have explored how the state ought to go about making decisions regarding CWF. Within the ethics systematic review, a number of retrieved articles considered what the appropriate approach would be to decision-making regarding water fluoridation. Several articles proposed that a careful decision-making procedure is the most ethically appropriate way to arrive at CWF decisions as such a process (done well) would allow for the careful distribution of information, a broad inclusion of diverse perspectives, and the communication of rationale and process between decision-makers and constituents.<sup>62,63,91</sup> Such processes would allow for robust public justification and could be responsive to local views.<sup>77</sup> Crucial to this approach would be a fair, accurate, and robust provision of accurate information about the impacts of water fluoridation and dental disease.<sup>50,73,81</sup>

### Implications for This Health Technology Assessment

The appropriate role of the state cannot be settled through an ethics analysis of a particular technology. The purpose of outlining this issue here is to show that CWF does, perhaps to a greater extent than other health technologies, depend on broader perspectives about the nature of the structure of society and the interplay between individual and collective interests. Policy-makers and leaders considering CWF will need to consider the socio-political context of their jurisdiction when making decisions regarding this technology. In general, there is strong ethics support within public health ethics in favour of governments advocating for and promoting the overall good of the populations they serve.

## Discussion

This HTA conceptualizes CWF as a public health intervention, so a public health ethics framework can be helpful to synthesize the multiple ethical considerations raised in the section above. There are several (though mostly similar) public health ethics frameworks which could be used to analysis CWF, the discussion will proceed using the one proposed by Childress and Bernheim<sup>92</sup> as it is comprehensive, and well supported in the ethics literature. The framework proposes that the ethical permissibility of a public health measure should be evaluated according to its effectiveness, necessity, restrictiveness of means, proportionality, impartiality, and the extent to which it has public justification. The following section considers CWF with each of these.

### Effectiveness

The intention of CWF programs is to improve the oral health of populations. As previously discussed, the review of the health outcomes evidence for this HTA (as reported in the Review of Dental Caries and Other Health Outcomes) has found that there is consistent evidence for an association between CWF and a reduction in dmft in children, a reduction in DMFS in children, a reduction in caries prevalence and an increase in the proportion of caries-free deciduous teeth in children, a reduction in caries in permanent teeth (measured using DMFS and DMFT) in both children and adults, and a reduction in caries prevalence and increase in the proportion of caries-free permanent teeth in children and adolescents.<sup>55</sup> This (in addition to other outcomes for dental health reported in the Review of Dental Caries and Other Health Outcomes) suggests that there is sufficient evidence to show that CWF does lead to improved oral health outcomes. With this finding, it is reasonable to conclude that CWF satisfies the effectiveness criterion in this framework. Given this evidence for effectiveness, along with the background assumption that any impact of CWF is within a

context of widespread use of other fluoride modalities (e.g., toothpaste), it is reasonable to question what the potential effects of cessation may be. Further evidence from jurisdictions that have stopped CWF will be necessary to understand the ethical implications of CWF cessation.

## Necessity

This criterion inquires whether the particular intervention is necessary to achieve the intended goal, or whether some alternative could achieve the same result. In the context of this HTA it raises the question about whether improvements in oral health could be achieved through methods other than CWF.

A systematic comparison of CWF with other fluoride delivery modalities or oral health interventions is beyond the scope of this HTA. Studies retrieved for this ethics analysis suggest that alternatives to CWF are less likely to be as effective and are likely to be more costly,<sup>78,79</sup> which would lead to the conclusion that CWF is necessary to achieve its intended outcomes, at least at the same level of cost. It would be premature to conclude this with certainty, however, as a systematic review of the literature to examine these comparative questions was not completed as part of this HTA. Further, there is insufficient data from communities who have ceased CWF, which again makes it difficult to determine both the necessity of CWF, and therefore the ethical implications of ceasing CWF.

## Least Restrictive or Intrusive Means

This criterion (discussed in some detail in the previous section) raises questions about whether the goal of the public health intervention could be achieved with methods that are less restrictive or intrusive to individuals and populations. One of the major ethical arguments against CWF is that it entails providing fluoridated water to individuals without their expressed consent, and, by virtue of it being added to the municipal water supply, is difficult to avoid. Other arguments have suggested that while CWF is restrictive and intrusive in the sense that it changes the nature of one's tap water in a way that may be difficult to reverse, it is comparatively less intrusive than other public health interventions because it does not require a change in behaviour, nor does it restrict the physical liberty of individuals.<sup>93</sup> Once again, a full analysis of this criterion requires that we have some information of the effectiveness of CWF comparators, which was not included in this work.

## Proportionality

The criterion of proportionality (also discussed in the previous section) says that an intervention can only be justified if its benefits are proportionate to its expected burdens. As indicated in the Review of Dental Caries and Other Health Outcomes, the evidence gathered suggest that CWF does achieve important oral health goals, with very little evidence of harms or burdens, apart from some incidence of fluorosis.<sup>55</sup> This suggests that CWF is a proportional public health intervention.

## Impartiality

Related to questions of fairness, the impartiality criterion inquires whether the public health intervention is applied consistently across demographics. Interventions that meet this criterion are applied based on objective health needs rather than criteria such as ethnicity or socio-economic class. As discussed in the section on equity above, many have argued that CWF is particularly democratic because, at least within the communities where CWF is in

use, it is available in every household, regardless of the neighbourhood or its occupants. In this way it does satisfy the criterion of impartiality.

## Public Justification

This criterion is based on a foundational view that governance decisions (including public health interventions) must provide the public with reasons, explanations, and justifications for the practice.<sup>92</sup> Rather than being a criterion for the technology itself, the question of public justification is an inquiry into the way CWF is implemented and operationalized. In communities where CWF was introduced as the result of a public process (e.g., a plebiscite) and where information about fluoride adjustment was readily available, it seems reasonable to conclude that CWF meets the criterion of public justification. It is also theoretically possible that CWF could be used in a way that does not satisfy this standard.

## Is Community Water Fluoridation Ethically Justified?

CWF is ethically justified because (per the evidence identified in the Health Outcomes review)<sup>55</sup> it effectively improves public oral health with few harms and side effects. It is also an impartial intervention because, within communities where it is available, it is provided to all households, irrespective of status or wealth. Even though there are strong ethical arguments in favour of CWF, it will remain ethically controversial because it is provided without the direct consent of those who receive the intervention. In the case of CWF, this can be ethically justified because its public health benefits are significant enough to override the concerns related to individual choice.

In December of 2018, the Public Health Agency of Canada's Public Health Ethics Consultative Group conducted an ethics analysis on CWF in Canada.<sup>94</sup> The findings of the report identified common themes found in this analysis and also provided recommendations to address gaps in current knowledge or specific needs. The report concluded that CWF is ethically permissible and justified from a public health benefits perspective.

This HTA's scope was to evaluate CWF, and not to systematically examine other oral health interventions, so it is not possible to compare CWF with other oral health using an ethics lens. This means that it is not possible to examine with certainty whether CWF is strictly necessary (i.e., that there isn't an alternative that would be equally effective) or whether CWF entails the least restrictive approach to attain its goals. Nevertheless, this examination of CWF alone indicates that there is sufficient ethics justification to provide CWF in communities.

## Summary of Relevant Ethical Issues

This report describes ethical issues related to CWF. As noted, separate reports on the assessment of the health outcomes,<sup>55</sup> economic considerations,<sup>59</sup> implementation issues,<sup>57</sup> and environmental impact<sup>58</sup> for CWF are available as part of the full HTA review on this topic.

CWF has been ethically controversial since its early implementation in the mid-20<sup>th</sup> century. The ethical debate surrounds four key concerns: respect for individual autonomy and choice, promoting benefit and avoiding harms, promoting equity and fairness, and the appropriate role of the state in imposing interventions among populations. Opponents of CWF may hold a position comprised of a combination of perspectives, which may include the view that CWF is a forced implementation that does not respect individual choice; that the evidence of

benefit for CWF is insufficient or that there is evidence that it is, in fact, harmful; the view that CWF reinforces inequity by creating harm for particular groups; and that CWF programs are not consistent with what should be the role of governments. Proponents of CWF may argue that the restrictions on individual choice are justified by the benefits created by CWF, that there *is* good evidence that CWF is beneficial and creates few harms, that CWF promotes equity by improving the health of those in society who are less well off, and that it is appropriate for governments to take steps to promote the health of the populations they serve.

Of note, varying perspectives on CWF can be a result of differing views on the facts (i.e., whether CWF improves oral health outcomes) and on values (e.g., how to balance considerations of autonomy with those of maximizing benefit). The ethics analysis works within the evidence gathered by experts who have developed other domains of this HTA. With this approach, it is taken to be true that CWF does improve oral health (see the Review of Dental Caries and Other Health Outcomes for more detail) and that it ultimately results in reduced financial burden, especially for private consumers and private insurance companies (see the Economic analysis for more detail).<sup>55,56</sup>

Overall, this ethics analysis concludes that CWF is ethically justified because it effectively improves public oral health with few harms and side effects. It is also an impartial intervention because, within communities where it is available, it is provided to all households, irrespective of status or wealth. It has not been possible to arrive at any conclusions about the ethics of CWF cessation, because there is currently insufficient evidence about the effects of cessation. Even though there are strong ethical arguments in favour of CWF, it will remain ethically controversial because it is provided without the direct consent of those who receive the intervention. In the case of CWF, this can be ethically justified because the balance of its public health benefits outweighs its measured harms, and are significant enough to override the concerns related to individual choice.

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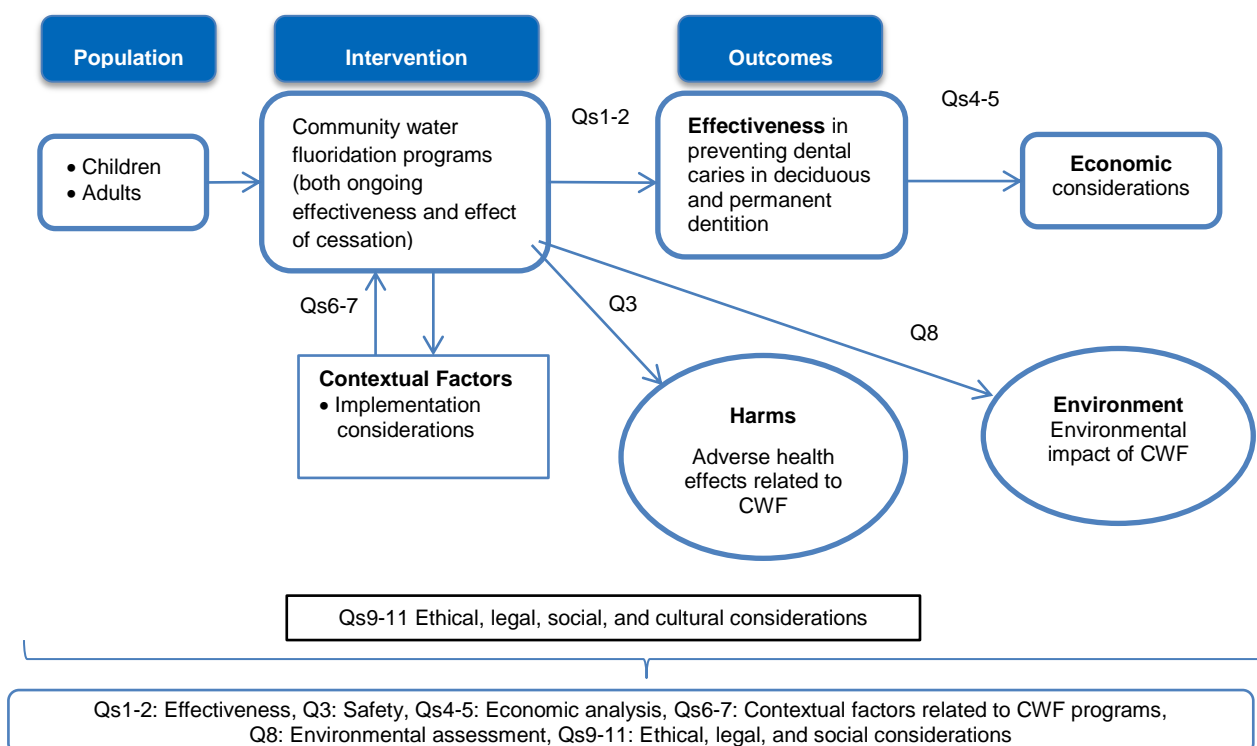
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## Appendix 1: Analytical Framework

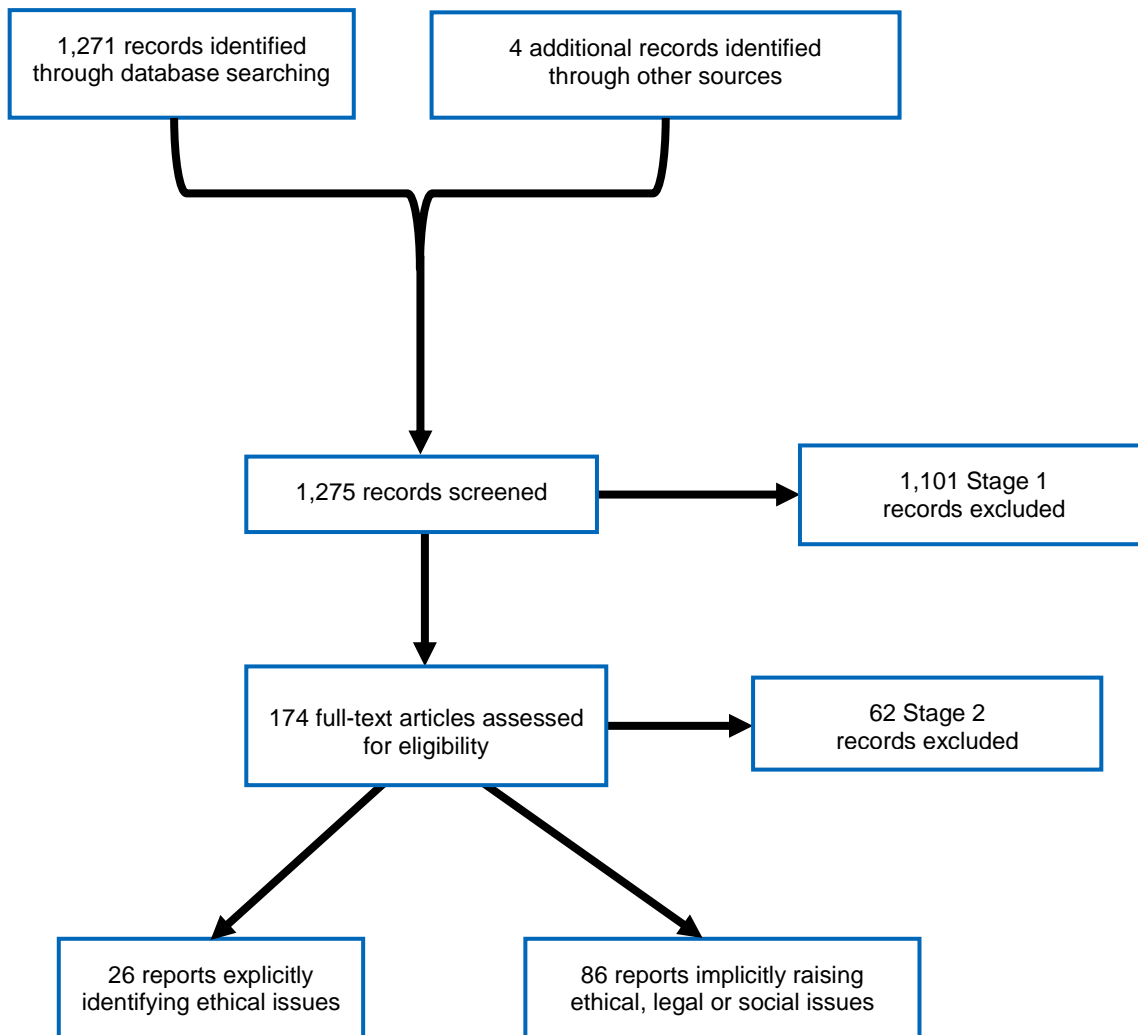
**Policy Question: Should community water fluoridation be encouraged and maintained in Canada?**



Research Questions	Methods
Q1. What is the effectiveness of community water fluoridation compared with non-fluoridated drinking water in the prevention of dental caries in children and adults?	Update of two published systematic reviews
Q2. What are the effects of community water fluoridation cessation compared with continued community water fluoridation, the period before cessation of water fluoridation, or non-fluoridated communities on dental caries in children and adults?	
Q3. What are the negative effects of community water fluoridation (at a given fluoride level) compared with non-fluoridated drinking water (fluoride level < 0.4 parts per million) or fluoridation at different levels on human health outcomes?	
Q4. What is the budget impact of introducing water fluoridation in a Canadian municipality without an existing community water fluoridation program from a societal perspective?	Budget impact analyses
Q5. What is the budget impact of ceasing water fluoridation in a Canadian municipality that presently has a community water fluoridation program from a societal perspective?	
Q6. What are the main challenges, considerations, and enablers to implementing or maintaining community water fluoridation programs in Canada?	Consultations with targeted experts and stakeholders Narrative summary of the published and grey literature Survey on implementation issues related to community water fluoridation
Q7. What are the main challenges, considerations and enablers to the cessation of community water fluoridation programs in Canada?	

Research Questions	Methods
Q8. What are the potential environmental (toxicological) risks associated with community water fluoridation?	Narrative summary of the published and grey literature Qualitative risk assessment
Q9. What are the major ethical issues raised by the implementation of community water fluoridation?	Review of the bioethics literature and analysis of ethical issues raised by reports answering Qs1-8
Q10. What are the broader legal, social, and cultural considerations to consider for implementation and cessation?	
Q11. What are the major ethical issues raised by the cessation of community water fluoridation?	

## Appendix 2: Flow Diagram of Literature Search and Selection Process of Articles Relating to Community Water Fluoridation



### Appendix 3: Summary of Issues and Sources

This appendix outlines the various arguments regarding water fluoridation which appeared in the texts included in the ethics systematic review. The evidence or premises presented as fact in these arguments are not evaluated in this section, nor have rebuttals to these arguments been included. The purpose of this section is to assist the reader in connecting the individual arguments with their sources.

General Theme	Argument Summary <sup>a</sup>	Reference
<b>Respecting Patient Autonomy</b>		
This is a key value in Western society that recognizes individuals' roles in determining their life course. In health care contexts, informed consent is a means of respecting patient autonomy by enabling patients to make an informed decision about their care.		
General consent	Mandatory water fluoridation puts fluoride in the water of all taps within a municipal system. Individuals are not given the opportunity to consent or withhold consent for fluoride in their tap water.	50,51,66-73
Consent for research	Provision of CWF is an experiment and the public, who are not able to give explicit or implicit informed consent, are the subjects.	72
Consent to medication	CWF is a compulsory medication provided en masse in haphazard doses without regard to whether the individual can benefit, and is expensive to avoid; thus, we are violating individual autonomy.	66,68,74
Conditions for meaningful autonomy	Individuals with few means may lack meaningful autonomy because they have few actual choices. Others, including children, lack autonomy so are not able to make informed choices.	73
	Meaningful informed consent requires that individuals have information about the potential risks and benefits that CWF poses to them, described to them by a qualified health care professional. This does not occur; therefore, individuals cannot provide meaningful informed consent.	70,77
	Individuals must know how to look after their teeth and should be informed of alternative methods for care.	81
	Without complete information about its benefits and risks, communities are not in a position to make an informed decision about CWF.	50
Overriding autonomy is not defensible	The violation of autonomy that occurs with CWF cannot be defended because benefits of fluoride can be obtained in other ways (e.g., supplements, fluoride mouth rinses).	51
	"That a procedure is safe and of benefit is not a sufficient criterion of its being ethically justifiable." Consent is still required.	75
	Tactics to influence (e.g., "nudging") may lead to better outcomes but does not address the problems that create the need to nudge in the first place.	83
Overriding autonomy is defensible	"...the degree of inconvenience involved in sourcing non-fluoridated water may frustrate a person's interests." This would be "counterbalanced by the potential inconvenience of finding fluoridated water should there be no CWF."	63
	"Unlike many other public health interventions, CWF does not require a change in a person's lifestyle so it does not coerce people into leading healthy lives."	63
	If consent is required for public health interventions that add substances, consent would also be required to remove harmful elements from an environment. This is not feasible and is also problematic because ascribing this weight to the importance of consent allows a small number to interfere with the collective good.	61,63
Promote and protect parental authority	"...fluoridation of public water supplies is a usurpation of parental rights by the public authority. The right and duty of providing for the health of their children, including their dental health, is a matter for the parents and not for the State."	61
	"...despite the vulnerability of children... it is usually not appropriate for the state to seek to promote the health of children in a way that infringes on the liberties of their parents."	62

General Theme	Argument Summary <sup>a</sup>	Reference
	...Water fluoridation may be a special case in which children could be reached directly without major infringements on their parents' liberties."	
Limits to parental authority argument	If this principle were "carried to extremes it would exclude the state altogether from the department of health, and would mean that every parent, in so far as his or her children's health is concerned, would be a law unto him or herself. Further, it should be understood that parental rights are really founded on parental duties; specifically, a parent has the right to provide for the health of his children <b>because</b> he has a duty to do so." This is duty "because children have a right to health and to the medical care necessary to achieve health. To put it another way, the right of the child to health and medical care is more basic and fundamental than the right of a parent to provide for the health. If parents in general cannot or would not provide safely and effectively for such care, then the state, as guardian of the common good, may lawfully step in and do so. This principle, we submit, justifies fluoridation by public authority, for it appears that there are not suitable, practicable, and effective means available to parents to ward off dental caries in their children."	61
Respecting faith	"Fluoridation restricts the right of religious liberty. The Christian Scientists who believe that the sick are healed by mental and spiritual influences, and not by medicines, are ardent assailants of the compulsory fluoridation. While they do not want to impose their beliefs on others, they feel that none should impose medical treatment, contrary to their religious convictions, on them."	61
Response to religious faith argument	"Freedom to religion is a very fundamental right. But freedom of religion has a dual aspect. Freedom of religious belief is an absolute right and the state is not justified in interfering with it in any way whatsoever. But freedom of profession and practice is a right which, obviously can have effects on others and on society in general. It may, therefore, be lawfully regulated and restricted if the common good demands it. If the state has a legitimate object in view, something which serves the general good of the citizens, then it may pass legislation to secure this object, even though such legislation may restrict the profession and practice of religion."	61
<b>Principle of Least Infringement</b>		
Ethical conflicts may be resolved in favour of an intervention if it results in the least possible infringement of individual or population autonomy and bodily integrity, as well as community health, among all available alternatives.		
	WF is an intrusive strategy as it results in mandatory consumption of artificially fluoridated water, even for those who may be harmed by this intervention. Its infringement on individual autonomy is higher than other sources of fluoride, which individuals may choose to use or not to use.	66,77
	Fluorides can be administered in other ways, e.g., as tablets or in solution. The only purpose of putting them into public water is to compel people to take them.	74
<b>Maximizing Benefits and Minimizing Burdens for Populations</b>		
This value articulates the importance of actions that confer benefit to the community or population as a whole. In health care, benefits are typically taken to be minimized incidence and prevalence of disease, minimized suffering associated with illness, and a reduction in preventable deaths. In HTA, we examine the extent to which a technology can be beneficial by looking at its clinical effectiveness.		
WF reduces health benefits for populations	Fluoride reduces the incidence of dental caries; therefore, it leads to better oral health.	51,61,66
	"Oral health is fundamental to general health and well-being. Poor oral health has significant effects on quality of life as a result of pain, discomfort, and impaired oral functioning."	63
	Apart from fluorosis, which is primarily cosmetic, fluoride is not associated with adverse health effects. This, in addition to its benefits, suggests that we are on balance promoting CWF for public health.	63,66,77
	"...some studies have identified lower rates of hip fractures among those exposed to optimally fluoridated water."	63
WF <i>may</i> create health benefits for populations	If it is established that the addition of fluorine to public water supplies involves no significant risk to life or health, then it may be added for the improvement of general dental health.	61,73
	"...it could be argued that the fluoridation of water might be a way of improving	62

General Theme	Argument Summary <sup>a</sup>	Reference
	environmental conditions in such a way as to promote people’s health.”	
It is not clear if WF presents a balance of benefits over harms to populations	“...there is no clear evidence that fluoride has any beneficial effects on the teeth of children, and it may be a threat to the millions of other people who will also be exposed.”	68
	Research is needed “to determine the effect of fluoridation on fluorosis, the health consequences of fluorosis, the impact of fluoridation on the environment, and the effect of fluoridation on multiple chemical sensitivities syndrome.”	51
	The full profile of side effects from WF has yet to be fully determined.	61,66
Precautionary Principle	The effects of water fluoridation are unknown and may be harmful. From a Precautionary Principle perspective it is ethical to reduce access to excessive fluoride intake given its potential to harm the body.	66,70,77
WF is harmful to populations	WF leads to fluorosis; therefore, we should not fluoridate.	66,68
	The fluorosilicic acid used to artificially fluoridate some water supplies are “contaminated with lead, arsenic, and mercury — major public health hazards for which no safe level exists.”	66
	WF will only help “the small fraction of children who do not brush their teeth with fluoride toothpaste or who would not use fluoride mouth rinse... But they may also miss out on the chronic toxic effects of swallowing fluoride: dental fluorosis, skeletal fluorosis, bone fractures, and hypersensitivity reactions.”	80
Aesthetic consequences	“Teeth also make a substantial contribution to physical appearance and oral health problems, and poor dental appearance can have negative impacts on earnings and employment opportunities.” WF causes fluorosis, which creates cosmetic differences in teeth.	63
<b>Proportionality</b>		
The Principle of Proportionality may be used to resolve the conflict between the ethical principle of beneficence (prevention of dental caries) and the non-maleficence (reduces an increased risk of fluorosis, possibly hypothyroidism, and bone fractures). I.e., The benefits of the intervention must be proportionately greater than the anticipated harm.		
	“...the modest anticipated benefits from artificial water fluoridation are not proportional to the significant adverse economic and health consequences of this strategy, such as the cost of artificial fluoridation, the aesthetic and psychological effects of dental fluorosis, and the likelihood of higher risks of bone fractures and hypothyroidism.”	66
	If the addition of fluorine to public water supplies would involve a significant danger to the life or health of any individual or groups of individuals within a community, whether that danger be immediate or long term, it would be morally wrong to do so, even though the addition would benefit the dental health of the whole community.	61,77
	“...a decision on the proportionality of an intervention can only be addressed once the legitimacy of its medicinal uses has been established. But if the test of legitimacy fails, then the product’s safety and efficacy are irrelevant.”	83
Necessity	With increasing awareness of other sources of fluoride, artificial water fluoridation is not a necessary tool for assuring optimal fluoride levels among community members, especially if other tools offer more choice to users.	50,66
	Tooth decay rates in many European countries have declined at the same rate as those in North American countries, which indicates that other factors may be responsible for decreasing dental cavities rather than water fluoridation, and that the benefits of fluoride (if any) may be overstated.	72
	Argument that WF reaches people who don’t have access to other methods to address oral health is not convincing because fluoridated toothpaste is affordable to most households and where it is not accessible, fluoride intake can be encouraged through subsidizing toothpaste, advocacy, and education.	66
	There are other methods of preventing dental caries; for example, by attending to the social determinants of poor oral health to improve dental hygiene. Changing social determinants	63

General Theme	Argument Summary <sup>a</sup>	Reference
	would require a broad range of government initiatives and time for them to make a difference, whereas WF is easier to implement and takes effect immediately.	
Capacity to gauge individual benefit	Medical experts do not have the full scope of expertise necessary to assess benefits to quality of life and other values relevant to the desirability of a particular technology.	50,80,81
Safety	Medicinal substances must be tested for safety and must comply with the regulator standards applied to the use of pharmaceutical products. In the US, no safety tests have been carried out on silicofluorides. Silicofluorides have been tested in Europe, and have been almost universally rejected for failing the safety standards. Staff working in the fluoride industry are not qualified to monitor the safety in manufacturing fluoride chemicals.	70
	“The amount of water drunk is extremely variable; consequently, the amount of fluoride imbibed will vary widely.”	74
	In WF, fluoride is delivered to everyone regardless of age, health, or nutritional status, without individual oversight by a doctor, and without control of the dosage.	71
	The safety and effectiveness of fluoridated water has never been demonstrated by randomized controlled trials — the gold standard study that is now generally required before a drug can enter the market.	71
Impact on environment	Fluoridation of drinking water could have a pollutant impact with serious consequences for aquatic ecosystems and biodiversity. It is clearly recognized that when living beings ingest fluoride, they largely accumulate it in their bodies, which can cause biochemical and morphological alterations.	77
<b>Distributing Benefits and Burdens Fairly (Equity)</b>		
This value describes broad social duties to consider matters of justice and to avoid disproportionately benefiting or burdening particular individuals or populations without clear justification.		
There are social inequities in oral health	The “literature indicates that the oral health of those from lower SES does not match that of their higher SES counterparts.”	63
	The dental profession provides dental services to those who can pay rather than to those with the greatest need, which results in an unequal distribution of services.	73
CWF promotes equity	Fluoride is effective in minimizing caries among all in the population, including those who lack other resources to seek dental care.	66,78
	Advocates of fluoridation contend that water supplies should be fluoridated on the grounds that everyone, regardless of SES, can benefit.	50,51,86
	“When it is available in public water supplies, fluoride is no longer a discretionary commodity available only to those who are familiar with its benefits, can afford it, and have access to it.”	51
	“The ability of CWF to reduce health inequalities may also be a function of its passive mode of delivery. CWF has the advantage over other methods (toothpaste, etc.,) of ensuring complete uptake of the measure at no added cost to the individual.”	63
CWF may promote equity	The justification that CWF promotes equity “could be used for fluoridation of water given that it may potentially improve dental health across the population, including in lower socioeconomic groups.”	62
We do not know if CWF promotes equity	“...there is no evidence to support the assertion that water fluoridation reduces social disparities in caries incidence.”	66
CWF leads to greater inequity	CWF leads to greater inequity because dental fluorosis disproportionately affects poorer children due to malnutrition.	66
	Fluoridation creates inequity that oppresses the entire community because it causes irreversible effects that affect children of all social classes.	83
Distribution of benefits and burdens	Those most likely to benefit from water fluoridation (the poor living in areas with limited access to adequate fluoride) are not necessarily those whose health outcomes are threatened by WF, such as infants aged less than six months, children from socio-	50,66,67

General Theme	Argument Summary <sup>a</sup>	Reference
	economically disadvantaged communities, those experiencing fluoride allergy and chronic renal disease, and people living in areas with a wide variety of natural fluoride from water and tea.	
<b>Protecting Vulnerable Populations</b>		
This value acknowledges that some populations are more likely not to receive what is owed to them and are less able to advocate for their own interests. It requires that such vulnerability be noticed and addressed through proactive steps.		
Protect by NOT fluoridating	We ought not to fluoridate water because the full profile of effects is still not known, particularly for vulnerable groups such as children and older adults.	66
Protect by fluoridating	Those most vulnerable in society would miss out on benefits of fluoride if it were not provided in tap water.	50
Children and infants — protect from CWF	“As an infant consumes a high level of fluid in relation to its body weight, its consumption of the fluoride dose could be eight to 10 times the proportion of an adult dose... A reassessment of the advisability of prescribing fluoridated water for infants would seem to be prudent.”	84
Children and infants — protect by CWF	“Children are born into a defined social stratum and are consequently exposed to the oral health benefits or vulnerabilities that come with it.” Children are “less able to make informed choices about their oral health, and are dependent on parents and caregivers to assist with or promote preventive measures such as tooth brushing. While other methods of delivering fluoride, such as the fluoridation of salt, milk, and toothpaste, have the advantage in that it is easier for adults to opt out of being exposed to fluoride, they have the disadvantage of reaching fewer children.”	63
	We can respect the personal freedom of someone eating too much sugar and not brushing their teeth. It ceases to be a personal freedom “when their children are encouraged, if only by example, to do the same.”	65
	“Children represent an especially vulnerable group in many public health contexts. This is true in dental health because they are susceptible to dental caries, are less able to make informed choices about their dental health, and are dependent on parents and carers to assist with or promote preventive measures such as tooth brushing.”	62
<b>Stewardship of Resources</b>		
This value describes the duties of those managing public resources to distribute these resources in a way that aligns with broad social norms of fairness, equity, and benefit.		
WF minimizes public costs	Reduced public costs from decreased caries justify the costs incurred by WF over time.	66
	The state is responsible for stewardship; encouraging responsible practice cuts down on having to provide so many resources to treat children.	81
	By reducing caries WF minimizes the need for restorative dental treatment thus affecting lifetime oral health utilization costs. Dental caries can result in serious infections requiring costly hospital visits and medical care. Fluoridation reduces these potential costs as well as costs for those provinces whose publicly funded health care systems include dental for children, seniors, and the poor.	51
	Dental hygiene choices impinge on the freedom of others when bad hygiene requires that a person visit a dentist to “mend the error of their ways.” It also impinges on others when this treatment is paid by public resources.	65
WF does not reduce public costs	Costs of WF and its associated maintenance and replacement of equipment do not justify the cost savings of reduced caries.	66
	Concerns about the potential negative economic consequences of fluorosis suggest that the benefits of CWF may be overestimated given that restorative dental treatment may be needed to treat fluorosis.	51
Minimizing private costs	A reduction on lifetime oral health utilization costs is significant given that most oral health care services are not included in publicly funded health care programs.	51
<b>Conceptualizations of Fluorine: Language, Metaphor, Comparison</b>		



General Theme	Argument Summary <sup>a</sup>	Reference
Fluoride is a medicine	Fluoride as medication.	70
	Certain formulations of fluoride (e.g., toothpaste, tablets, and drops) are formally registered as ingestible drugs or medicines in many parts of the world; however, some fluoridating chemicals (e.g., fluorosilicic acid) are not registered as medicines by governments that permit CWF (UK, US), or as in New Zealand, are expressly not considered medicines if they are delivered in CWF.	68,70,83
	“Were [fluoride] to be a registered medicinal treatment, it would immediately be removed from use, in the same that any other drug would be recalled under a similar onslaught of evidence for adverse effects.”	70
	Fluoridating chemicals should be subject to the procedures and testing that occur with all other pharmaceutical products, including formal licensing, quality control in manufacture, and safety testing, and should be administered according to established codes of ethics.	70
	The US FDA accepts that fluoride is a drug, not a nutrient, when used to prevent disease. Therefore, fluoridating water is a form of mass medication.	71
	Fluoridation is not a medication because it prevents disease, rather than treats it.	80
Fluoride as substance under research	Provision of fluoride in community water supplies can be viewed as an experiment with participants.	70,72
	Ethical parameters and procedures that guide research should be applied to CWF programs.	70
Fluorine as poison	“...one of only two chemicals authorized for WF — sodium fluorosilicate — is recognized as a scheduled poison under the Poisons Act of 1972.”	68
	Silicofluorides are obtained from the effluent scrubbers of the phosphate fertilizer industry, which is highly toxic hazardous waste.	70
Fluorine as fortification	Fluoride as food fortification.	63-65
Fluorine equivalent to chlorine and water treatment	Chlorine is introduced to water to destroy germs. Fluorine is added to the water to build up resistance to germs. No one objects to chlorine, therefore no one should object to fluoride.	61-63,65
	“Unlike all other water treatment processes, fluoridation does not treat the water itself, but the person consuming it.”	71
Fluorine as essential nutrient	Fluoride is a natural trace element essential to the body’s nutrition. Any water authority that does not optimize fluoride concentration in water supplies is failing to fulfill its duties.	80,84
<b>Duties of the State</b>		
There are various perspectives on the role of the state in promoting the public good. In nations like Canada, it is generally accepted that the state has some role in preserving and promoting the public good, though perspectives about how this can be done vary.		
Shared responsibility	There is an open question about who is responsible for teeth. This may be a shared responsibility between individuals, professionals (dentists), and the state.	81
Duty of state to promote common good	The state has a duty to promote the good of its citizens. Individual liberty is not absolute. If CWF does promote the public good and there is no other means to achieve this good, then it is permissible, even if it limits the rights of some citizens.	61,73,84
Role of state to promote good and established Canadian values	“The liberal individualist argument against involuntary medication of populations may initially seem compelling. However, Canadian society has established a core set of values that allow for the infringement of individual rights in certain instances... Although we are a society dominated by individual rights, Canadians accept that some public policies must put the common good above the desires of some individuals.”	51
State can override autonomy to promote good only if there is evidence of benefit	In some cases it would be acceptable to set limits on the population for the purposes of promoting public health (e.g., seatbelts). For such an action to be justified, it must be clear that with the restriction, there is a greater balance of benefits of risks than when individuals would be free to opt out of an intervention.	62,67

General Theme	Argument Summary <sup>a</sup>	Reference
State ought not to limit individual autonomy in the name of health benefits	The state ought not to have authority to violate individual autonomy just because doing so would be of benefit for children.	61,68,75,83
The state may override individual choice only when the health impacts are serious	“Medical ethics unequivocally demands that the wishes of the individual must take precedence over actions imposed by the state, unless there is a valid and wider public health concern. A state’s interest may legitimately override an individual’s wishes if a person with a potentially life-threatening and contagious disease, such as measles or Lassa fever, refuses to accept treatment and/or quarantine. Obviously, tooth decay does not qualify as such a disease, requiring the state to usurp individual rights. States continue, nonetheless to insist on their “police power,” having convinced the public through press releases that fluoridation is completely benign.”	70
State’s role in promoting health can conflict with professional role	“State public health policies target communities, not individuals, and the strategies adopted include a wide range of interventions. Some, such as garbage collection, sanitation, and pest control, target environmental threats to health, but others include invasive interventions, such as vaccination programs, that involve medical intervention at the personal level, which really falls within the remit of medical practice. The jurisprudence that regulates public health practice at the community level has the potential to be in tension with that applying specifically to medical interventions at the personal level.”	83
CWF in some countries violates its own laws and regulations	“Those who elect not to have their dental caries treated present no public health risk to the state, so the imposition of fluoridation is therefore covered by Article 2 [of the Council of Europe’s Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine]”, which affirms that establishing that the wishes of an individual in respect to his or her exposure or treatment for medical conditions takes precedence over state objectives.	70
	“...the Council of Europe’s Convention on Human Rights and Biomedicine, Article 5, prohibits any intervention in the health field for which free and informed consent has not been given, and from which the individual cannot withdraw at any time.” (Note that the UK has not ratified this convention on the grounds that it is “too restrictive.”)	83
How to make decisions about CWF	The most appropriate way of deciding whether to fluoridate the water supply is to rely on democratic decision-making procedures. These should be implemented at the local and regional, rather than national, level because the need for and perception of WF varies between areas.	63,91
	“...public justification implies transparency of the authority to justify and continue the practice of water fluoridation... as well as allowing the parties involved to contribute to the development of policy.”	77
	If we consider fluoridation within the domain of social policy, it shifts the focus away from notions of equal rights and focuses instead on equal access to health care.	81
	“Because of these ethical issues decisions about fluoridation, we must take account of public opinion, but before lay people can make a meaningful contribution to the debate, they need an understanding of the science. This is difficult because there are, inevitably, uncertainties and the evaluation of the scientific evidence is to some extent subjective. Often the media are more interested in highlighting disagreement and controversy than in establishing the extent of consensus, and this leads to confusion and distrust.”	67
	One must be honest with his or her dealings with others. WF requires PH professionals to be honest and upfront in their presentation of the risks and benefits of fluoride.	50,73

CWF = community water fluoridation; HTA = health technology assessment; PH = public health; SES = socio-economic status; WF = water fluoridation.

<sup>a</sup> The following arguments been identified in the literature, but have not specifically been evaluated for accuracy.