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Water fluoridation between public health and public law: an assessment of regulations across countries and their preventive medicine implications

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Keywords: Public health; drinking water; fluoride; law; regulations; policy
Parole chiave: Sanità pubblica; acqua potabile; fluoro; leggi, regolamenti; politiche

Abstract

Background. *Among health professionals and health policymakers concern is growing as to the difficulty of balancing the prevention of dental caries through cost-effective interventions and the need to limit unnecessary exposure of the population, and especially children, to environmental chemicals. In this respect, the use of water fluoridation to prevent tooth decay epitomizes the dilemma by raising questions relevant to both public health and public law, ranging from the balance of public health and medical self-determination, the division of powers between local or national authorities over water fluoridation, and the need to avoid the adverse effects of socioeconomic inequalities as well as both under- and over-exposure.*
Study design. *We carried out a narrative review by searching the relevant literature about the laws and rules related to drinking water fluoridation at the community level in the US, UK, and Europe, in order to discuss how the issue is handled from both a public health and public law perspective.*
Methods. *Sources of data for this review were the biomedical and legal literature retrieved by searching online databases, and websites of public health and legal institutions.*
Results and Conclusions. *We found that water fluoridation is still largely adopted throughout the US, while in the UK and particularly in the European Union only a minor part of the population is subject to it. In addition, the recommended and maximum allowed amounts of fluoride in drinking water are being adapted to the public health recommendations and the new regulations, within an evolving evaluation of the epidemiologic evidence and the risk assessment currently in progress by two major regulatory agencies, the US National Toxicology Program - NTP and the European Food Safety Authority - EFSA. Under a comparative public law perspective, the three investigated legislations are facing a reassessment of their policies and regulations, to allow for effective and safe public health measures in the field of water fluoridation and more generally for a preferred use of topical fluoride for caries*

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prevention. A consistent trend across these legislations is the choice to centralize at the national level regulatory and management issues related to water fluoridation, and to carefully balance benefits for dental caries prevention in children and the potential risks of systemic overexposure associated with excess fluoride intake, by promptly responding to the evolving indications by the scientific community and the public health professionals.

Introduction

The feasibility and opportunity of water fluoridation is an old and relevant question that raises issues for both public health and public law (1, 2). The possibility that optimal fluoride intake through drinking water may prevent dental caries in both developing and adult dentition is a long-recognized major public health issue (3-5) that has long attracted interest in dental medicine and is supported by several studies (6-8). At the beginning of 1945, in a Michigan community, the urban area of Grand Rapids, sodium fluoride started to be added to drinking water aiming at reducing the incidence and prevalence of dental caries, particularly in children. Such public health measure has progressively expanded in the US up to the most recent years, leading to a percentage of coverage of the population close to 75% (9). As outlined by the Center for Disease Control, "As of 2020, more than 208 million people, or nearly 3 in 4 Americans who use public water supplies, drank water with enough fluoride to prevent tooth decay." (10). However, such practice has also induced considerable controversies in light of the potential risk associated with high fluoride exposure and divergent perceptions across countries, health agencies, stakeholders, and activists as to the safety of such a practice (8, 11-14).

Many dental scientific societies still support community water fluoridation as an equitable and cost-effective strategy to provide optimal and widespread fluoride exposure (15). However, in some countries, bottled water is more commonly consumed than tap water for drinking purposes, thus limiting the action of tap water only to topical effects deriving from other daily activities such as cooking, brushing teeth, and rinsing (16). Furthermore, in the recent past it has been firmly established that the topical preventive effects of fluoride are significantly greater than the systemic effects, which are also mostly limited to the pre-eruptive dental period, and thus benefit only young children (11, 17).

In addition, water fluoridation only partially accounts for the total amount of fluoride exposure, specifically due to intake from foods and other beverages naturally rich in fluoride, such as certain types of fish or teas and some bottled waters (10, 18, 19). Also, fluoridated milk and salt are available in some countries where they are typically applied in school settings through health and nutrition programs, especially in communities with high risk of caries (20-22). Fluoride supplements may be considered an additional source of fluoride, but they have limited use, being currently recommended only for vulnerable individuals at high risk of caries, especially children and adolescents, where other sources of fluoride are unavailable (16, 17, 22). Overall, topical fluorides represent the first-line recommendation given their optimal risk-benefit balance, but the possible accidental ingestion of topical home-use or professionally-applied fluoride products only accounts for a minor source of fluoride exposure (10, 17, 23-25). Therefore, fluoride from drinking water remains a rather relevant source if compared to others (10, 18).

Currently, two major assessments about the established benefits and the potential risks of fluoride exposure are underway (18, 26), thus reflecting the growing interest in the general population and the scientific literature about the effects of fluoride on human health (27-33). Unsurprisingly, policies of public water fluoridation elicit a wide array of legal issues in different countries. The most evident problem is that even where the decision to fluoridate public waters is not taken by experts in administrative agencies but by an elected body, it still impinges on the minority of individuals who disagree with the policy. In this respect, water fluoridation has been described as a form of "mass medication" (34) that interferes with freedom of choice (35) and contrasts with the right to medical self-determination and informed consent (36). To the extent that general public health considerations trump some individuals' right to medical self-determination, water fluoridation resembles compulsory vaccination (37). However, other legal aspects are relevant to water fluoridation programs, one prime example being the federal arrangement of the health system, which may lead to major differences in fluoridation policies. It is no accident, in this respect, that unsuccessful dental caries prevention programs can at times be explained by the "lack of national policy for oral health" (38).

Considering such controversies, as well as the expanding interest of dental and public health professionals in reviewing the topic related to fluoride use, efficacy in caries prevention and safety (39, 40), we aimed to perform this narrative review in order to provide an updated assessment of the implementation of water fluoridation, focusing on the related public health perspectives and public law regulations, in some Western countries.

Methods

We searched the Scopus and PubMed online databases, and we scanned the websites of major public health and public law institutions to identify pertinent publications dealing with water fluoridation and the legal framework of such an intervention using terms related to "water" and "fluoridation/fluoride". We focused in this endeavor on three industrialized contexts of major relevance from a public health perspective: Europe (European Union and the UK), and the United States.

Results and Discussion

With regard to the North American experience, there are comprehensive sources of data for the US regulatory approach to the issue of drinking water fluoridation and its extension, currently reaching around 75% of the total population with no substantial changes over time (41). Since its beginning the large use of fluoridation in public water supplies of the US found its basis in recommendations by the US Public Health Service, which originally (since 1962) suggested achieving drinking water fluoride concentrations of 0.7-1.2 mg/L, and more recently (since 2015) lowered the suggested level to 0.7 mg/L (42). Though such Public Health Service guidance and recommendations were advisory, and not regulatory, in nature, the public health supply managers promptly complied with these indications, by lowering the fluoride tap water levels to maintain the protective effects on dental caries incidence while at the same time avoiding excess exposure to fluoride, in order to take into account the health concerns and reduce the opposition to such a practice by many individuals and activists (42). These recommendations followed a comprehensive assessment of the beneficial and adverse effects of fluoride performed by the US Environmental Protection Agency (EPA) and the US Department of Health and Human Services (HHS), which worked together to maintain the benefits of preventing tooth decay while preventing excessive exposure (43). Considering the federal nature of the American constitutional system, the issue of tap water fluoridation is regulated at the state level and therefore there are many different rules and laws for each state. A comprehensive summary and review of such rules, including both statutes and the regulations in each of the US States was made available by the Network for Public Health Law (44). In summary, most states have both statutes and regulations providing a framework about when and how to add fluoride to public drinking water supply systems, provided that such supplies serve more than a minimum number of residents (generally above a few thousand individuals). However, there are some exceptions, i.e. states in which no statute and regulation for water fluoridation have been defined and established. Among these are Arizona, the District of Columbia, Maryland, North Dakota, Oklahoma, Rhode Island, Texas and Wyoming. Regarding the power of public authorities to add fluoride to drinking water for dental caries prevention, so far the US judicial system buttressed the legitimacy of fluoridation with several court decisions upholding the practice (45). In some cases, the argument for the decision rested on considering fluoride as a nutrient and not a medication that may interfere with individual freedom (46). In addition, the US Supreme Court has so far denied review of fluoridation cases several times, by stating that there was no involvement of substantial federal or constitutional issues (46). However, there is an ongoing judicial ligation over this key issue, taking into account the new risk assessment on fluoride neurotoxicity performed by the National Toxicology Program (26), and new decisions of the US courts are expected in the future (47).

In the UK, community water fluoridation programs have been effective in improving dental caries prevention and more generally dental health, a major public health target and achievement. However, differently from the US, only a limited part of the population was subject to water fluoridation programs, since only about six million people in England (10% of the national population) are located in areas where fluoridation programs have been enforced, predominantly in the Midlands and the North East (7, 48-50). Such programs were established under the legislation composed by the so-called "Water Act" issued in 2003 and a Statutory Instrument adopted in 2005, which provided indemnity for water companies undertaking water fluoridation, and by the Health and Social Care

Act approved in 2012, a key piece of legislation that returned the decision-making power to local authorities. Such local authorities were allowed to take the steps deemed appropriate to improve the public health of the local population, including oral health, also by adopting water fluoridation interventions (51). However, the growing awareness of the need to balance established benefits and potential harms from fluoride exposure, as well as other legal and management considerations highlighted a major issue in the policy concerning the British experience: the need to move the management of such a public health issue from a local to a central level (52, 53). This was the case in light of the growing evidence of technical and economic difficulties of the local authorities in regulating many public health issues including water fluoridation, and to avoid substantial inequalities among different population groups and areas of the country. A move toward centralization thus inspired the most relevant piece of legislation in health reform and public health adopted by the UK government, the Health and Care Act 2022 approved in that year by the British Parliament (54). Such a key piece of legislation effectively transferred to the central Authorities – namely, to the Secretary of State for Health – the legal power to either implement or terminate water fluoridation schemes in England, a responsibility previously resting with the local authorities (49, 53). This development will likely allow more timely coordination with the update of the scientific assessment of water fluoridation risks and benefits, a balanced approach across the local communities unrelated to local social and political disparities and inequalities, and better management of the health-based needs of the local communities (48, 55-57). In such a case, the legal choice to transfer local/regional responsibility to a central authority is likely to prove beneficial from a public health perspective, despite this being a very different choice from those currently adopted or being implemented in countries such as Italy (58). The main features of the new approach for community water fluoridation defined by the Health and Care Act also bestow on the Secretary of State the following responsibilities: to define the extent (in terms of fluoride concentration) of water fluoridation, the monitoring of the populations subject to fluoridated water consumption, the reporting of potential health effects, and the duty to undertake public consultation about the water fluoridation practice in certain circumstances, either in case of termination of current practices or establishment of new ones (59). Overall, the Secretary of State has therefore the full power to introduce, vary, or terminate water fluoridation schemes, and in addition, it can take up the revenue costs of the fluoridation interventions. Currently, the maximum permitted value of drinking water fluoride is 1.5 mg/L, the same recommended level by WHO for naturally occurring fluoride to prevent dental caries (60), and slightly higher than the WHO recommended optimal fluoride level following artificial water fluoridation of 1.0 mg/L (61). However, the intended level to be achieved to prevent tooth decay in the UK is 1 mg/L. In most British areas, fluoride concentrations are low i.e. in the order of 1 mg/L or less, though there are areas naturally rich in fluoride in the order of 0.5 mg/L or more (51).

In the European Union, the naturally occurring tap water fluoride levels are generally rather low, with significant regional differences due to geological origin. Fluoride levels in natural drinking water within the EU States indicate large differences within and across countries, e.g. Ireland 0.01-5.8 mg /L, Finland 0.1-3.0 mg/L, Germany 0.1-1.1 mg/L, and Italy (61). However, levels of fluoride may largely differ depending on soil origin and rock composition (62), e.g. in Italy levels generally in the range of 0.1-6.1 mg/L may also reach 30.2 mg/L in some areas of volcanic-sedimentary origin (19, 63-66), with also additional concerns about the feasibility of water fluoridation when different sources of drinking water are mixed in the aqueduct system (1, 67). Regarding the maximum allowed concentration of fluoride in drinking water, the EU legislation has not varied over the last decades. The 1998 Council Directive 98/83/EC was originally established to keep fluoride levels in both natural water and following fluoridation intervention in drinking water for human consumption <1.5 mg/L (61), and the most recent EU Drinking Water Directive (2020/2184, adopted December 2020, in force since January 2021 (68)) has confirmed such a maximum allowed level. When considering these regulations, the rather elevated naturally-occurring water fluoride concentrations in some countries including a few Italian areas (69), the low methodological quality of most epidemiologic studies about water fluoridation (7), and some concerns about systemic low-dose fluoride overexposure in children as compared with the efficacy and safety of topical fluoride administration through fluoride toothpaste, rinses and varnish applications (15, 70), appear to have been major drivers of caution about wide-scale water fluoridation in many countries including the EU ones. The European Commission Scientific Committee on Health and Environmental Risks (SCHER) has assessed the health effects

(benefits and potential harms) of water fluoridation, yielding a prudent overall evaluation of the issue, suggesting little adverse effects of water fluoride levels in the 0.8-1.5 mg/L range, and highlighting the need for further epidemiologic and analytical research in the field (61). Overall, the practice of water fluoridation is almost entirely absent in the EU countries, with the exception of Ireland and the partial exception of Spain (71), for a broad spectrum of reasons (72). From a legal perspective, there is currently no mandatory law or regulation by the EU either to force or ban water fluoridation in the member states, thus deferring to the single countries the responsibility for such a possible action, provided that the standard for fluoride drinking water level is not exceeded. As previously noted, the European countries differ in terms of naturally occurring fluoride levels in drinking waters, as well as regarding the use of fluoridated salt, milk, and toothpaste, thus making the exposure pattern across the EU very uneven also with reference to caries prevention. Conversely, derogations from drinking water quality standards have been reported in some regions due to the high fluoride levels in groundwater (73, 74). In principle and despite the very rare occurrence of water fluoridation in the EU, there are no EU bans against the implementation of water fluoridation intervention, since the EU Commission has clarified that no such legal impediment to water fluoridation exists in any member state (EU Petitions 0210/2007 and 0211/2007), nor are there international treaties limiting the right of member states to avail of water fluoridation programs (75).

Conclusions

Overall, an overview of the current legislation concerning water fluoridation indicates a trend toward homogenization of competencies and regulations across different industrialized contexts such as the US, the UK, and the EU, despite persisting differences in the choices and policies across them. From a public law perspective, homogenization of legislation enables all domestic authorities to take action in assessing the possible need for water fluoridation at the national level and the preferred fluoride concentrations. Policy choices should consider the public health issues related to both decay prevention and avoidance of overexposure to environmental chemicals, promptly reacting to any short-term changes in the scientific evaluation of these complex issues and overruling economic and organizational limitations, in line with similar trends currently occurring in other countries (15, 76). Despite some differences, these examples of legislation from the three industrialized contexts clearly indicate how public law may (and should) effectively take into account and comply over time with public health recommendations and offer the possibility to swiftly implement them.

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Riassunto

La fluorazione delle acque tra sanità pubblica e diritto pubblico: una valutazione comparata della normativa di alcuni Paesi e delle relative implicazioni di medicina preventiva

Introduzione. Tra gli operatori e politici sanitari è sempre maggiore la preoccupazione riguardo alla difficoltà di bilanciare la prevenzione della carie, specialmente nei bambini, attraverso interventi economicamente vantaggiosi e la necessità di limitare l’esposizione a sostanze chimiche ambientali se non strettamente necessario. A questo proposito, l’uso della fluorazione dell’acqua per prevenire la carie sintetizza tale dilemma sollevando questioni rilevanti sia per la sanità pubblica che per il diritto pubblico, che vanno dall’equilibrio tra salute generale e diritto all’autodeterminazione in campo sanitario, al riparto delle competenze tra autorità locali o nazionali sulla fluorazione dell’acqua e alla necessità di evitare gli effetti negativi derivanti dalle disuguaglianze socioeconomiche, oltre che della sotto e sovraesposizione.

Disegno dello studio. Nel contesto di una *narrative review*, abbiamo valutato la letteratura scientifica pertinente nonché le leggi e le norme relative alla fluorazione dell’acqua potabile a livello comunitario in Stati Uniti, Regno Unito ed Europa al fine di illustrare come la problematica venga gestita dal punto di vista sia della sanità pubblica che del diritto pubblico.

Metodi. Le fonti dei dati per questa revisione sono state principalmente banche dati scientifiche *online*, al fine di individuare la letteratura biomedica e giuridica più recente di potenziale interesse sugli aspetti giuridici e di sanità pubblica della fluorazione delle acque.

Risultati e Conclusioni. Dall’indagine effettuata emerge come la fluorazione dell’acqua sia diffusa in tutti gli Stati Uniti, mentre nel Regno Unito e in particolare nell’Unione Europea solo una piccola parte della popolazione ne è soggetta. Inoltre, le quantità raccomandate e massime consentite di fluoro nell’acqua potabile vengono costantemente adattate alle raccomandazioni di sanità pubblica, nell’ambito di una valutazione del rischio in evoluzione a causa di recenti studi epidemiologici e attualmente in corso da parte delle principali agenzie di regolamentazione, in particolare il *National Toxicology Program* statunitense e la *European Food Safety*

Authority. In una prospettiva di diritto pubblico comparato, nelle tre legislazioni esaminate sono attualmente in via di implementazione politiche e normative più adeguate, al fine di consentire misure di sanità pubblica più efficaci e sicure nel campo della fluorazione dell'acqua. Una tendenza coerente in queste legislazioni è la scelta di centralizzare a livello nazionale le questioni normative e gestionali legate alla fluorazione dell'acqua e di bilanciare attentamente i benefici per la prevenzione della carie nell'età evolutiva e i potenziali rischi di sovraesposizione associati all'assunzione sistemica di fluoro, rispondendo tempestivamente all'evoluzione delle indicazioni della comunità scientifica e degli operatori sanitari.

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