8-2017

Understanding Federalism and U.S. Fluoridation Policy: The Policy Landscape of U.S. Fluoridation Policy

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UNDERSTANDING FEDERALISM AND U.S. FLUORIDATION POLICY: THE POLICY LANDSCAPE OF U.S. FLUORIDATION POLICY

A Dissertation
Presented to
the Graduate School of
Clemson University

In Partial Fulfillment
of the Requirements for the Degree
Doctor of Philosophy
Policy Studies

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by
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August 2017

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ABSTRACT

In 2015, the Federal Panel on Community Water Fluoridation finalized a recommendation setting a fixed 0.7 mg/L optimal water fluoridation level for the United States. The announcement was made in the Federal Register in 2011 and allowed for a period of public comment and scientific review before being finalized. Since the original 1962 optimal range recommendation, community water fluoridation has been a decentralized policy environment allowing for local decision-making in setting water fluoridation levels. The finalized 2015 policy recommendation attempts to centralize policy decision-making to reduce the risk of overexposure while maintaining decentralized implementation. This dissertation addresses the following research question: *Why is U.S. fluoridation policy implemented in a decentralized rather than a centralized fashion?*

The research uses a policy cycle framework approach to understanding the water fluoridation policy process and identifies potential problems with a central policy recommendation in a decentralized policy environment and explores policy alternatives. A mixed methodology was used to analyze the policy formulation and implementation stages of the policy process. A quantitative analysis was utilized to understand policy implementation at the local level. Results indicate that the recommendation was likely effective in narrowing the variability of fluoridation levels. Further, the 0.7 mg/L recommendation was likely met since the policy change. A qualitative analysis addressed potential missed opportunities during the formulation stage of the policy process. Analysis revealed: positive results in stakeholder perceptions of engagement and in meeting the recommendation, a slight preference for state

policy recommendations, and mixed results for exploring alternate models, equitability of implementation, and consumer opt-out options.

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DEDICATION

First and foremost, this dissertation is dedicated to my wife, Sabrina. Without her understanding and personal sacrifice, none of this would have been possible. I also dedicate this dissertation to my beautiful children Kayleigh, Hunter, and Declan Walker. I did this for you and for our future. I hope my educational pursuits will encourage each and every one of you to find your own paths and set and pursue your own goals. I also dedicate this to the other doctoral inspirations in my family, my mother, Dr. Mary K Walker, and my grandfather, after whom I am named, Dr. Thomas C Walker, Sr. Even though we never met, I know you would have supported this endeavor and been very proud of my accomplishment. Only you know the miles I have travelled to reach this milestone.

ACKNOWLEDGEMENTS

Clemson has been a wonderful place for me and my family. As such, there are many I wish to acknowledge. I would like to acknowledge first and foremost, Dr. Lori A Dickes, who has mentored me and encouraged my educational and professional growth and development. I would also like to thank Dr. Jeff Allen, for his guidance through some of the most critical pieces of my doctoral program. Both of you have sacrificed time and energy and put your reputations on the line for me and I am forever grateful. I would also like to thank Dr. Bruce Ransom for introducing me to Lori and Jeff and for fighting for me to gain admittance and stay with the program at Clemson. Last but not least, I wish to thank Dr. William Haller, who introduced me to sociological perspectives on policy actors and exchange I would have otherwise missed.

I would also like to acknowledge many in the Policy Studies department whom I have had the pleasure to work with over the years. First I would like to acknowledge Carolyn Benson, without whose application guidance, I may have never been accepted. I would also like to acknowledge my preliminary study group of Cindy Roper, Sonya Crandall, Pat Apperson, and Elif Can-Sener, I learned the most and finally put it all together that summer. Thanks to the Policy Studies broader family I have worked with over the years: Shawn Nanney, Aury Kangelos, Dr. Rob Carey, Dr. Mark Mellott for letting me teach Perspectives, Alfred Bundrick, and Dr. Elizabeth Crouch. Last but not least, Dr. Fidelis Okonkwo for crossing the finish line with me and pushing me this last year.

I would like to acknowledge other family for their support: Matthew, Allie, and Owen Walker, Karen O’Connor, Karen Brown and Brown family, David and Therese Marshall, Phil and Roberta Stalvey, Susi Frye, and Thomas C. and Pam Walker, Jr.

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Chapter 1: Introduction

Millions of Americans drink treated water every day. The vast majority drink surface water treated with fluoride to achieve an important public health outcome. For the last 50 – 70 years, water fluoridation has become ingrained into the majority of communities across the United States. For some, this policy area is seen as trivial or, indeed, overlooked. However, it is a significant public health achievement accounting for significant declines in dental caries. Water fluoridation was named as one of ten great public health achievements of the 20th century along with: vaccination, motor-vehicle safety, safer workplaces, control of infectious diseases, decline in deaths from coronary heart disease and stroke, safer and healthier foods, healthier mothers and babies, family planning, and recognition of tobacco use as a health hazard (CDC, 1999). Why do we care about water fluoridation policy? This policy area affects millions of Americans on a daily basis and cuts across professions from public health experts to water management professionals. Water fluoridation is an important, outcomes driven, public health policy which requires implementation at the local level. It is important to get it right, to achieve the desired outcome without negative side effects.

Public health achievements, such as the ones mentioned by the Centers for Disease Control (CDC) as significant in the last century, made significant impacts on American longevity. Water fluoridation policy exemplifies epidemiologic structured intervention to prevent serious infectious and communicable diseases in the community (CDC, 1999). Dental caries were a common ailment in the United States until the beginning of the 20th century when scientific measures were developed to index caries and provide context for their distribution and prevention (CDC, 1999).

Water management and the provision of treated drinking water represents a hybrid between natural resource management and public health outcomes. Large scale water provision is now commonplace, but delivering reliable life-sustaining drinking water is not without its challenges. There are many chemicals both natural and artificial that contaminate surface and ground waters; they require monitoring at all levels of government to prevent negative exposure levels. Getting it right at the water treatment level is complex and requires significant engineering knowledge and practice.

The complexities involved in developing and enforcing public health policy at multiple levels of government could be seen as difficult. When developing public health policy that must be implemented across professions, it could add a layer of difficulty to this desired outcome. Developing a public health policy which cuts across professions and descends multiple federalist layers without federal enforceability could be considered extremely difficult to achieve. This provides some foreshadowing to the research endeavor of this study.

The Federal Panel on Community Water Fluoridation finalized a policy recommendation in 2015 to reduce the fluoride level in artificially fluoridated water systems from the previous range of 0.7 mg/L – 1.2 mg/L to a fixed 0.7 mg/L across the United States. The recommendation was finalized after several years of public comment and scientific review beginning in 2011. The goal remained the same: continuing the reduction of dental caries while preventing dental fluorosis levels. One of the challenges with this change is that the new policy is a centralized recommendation in an inherently decentralized policy environment across professions. Additionally, the policy recommendation is not enforceable at the federal level and requires implementation at state and local levels.

A gap in the research was identified after making the policy recommendation; that is, there was no opportunity for stakeholder feedback until after the recommendation had been made and released for public comment. Additional research is needed regarding those who are charged with implementing this policy recommendation, especially research demonstrating the potentially complex nature of implementing a centralized policy in a decentralized policy area. Through this study, these two research opportunities will be explored, with future research implications and opportunities identified. The final policy recommendation shifting from a range of 0.7 mg/L – 1.2 mg/L to a flat 0.7 mg/L leads to the primary research question: Why is U.S. fluoridation policy implemented in a decentralized rather than a centralized fashion?

This endeavor is a much needed supplement and addition to water fluoridation policy research. It explores, with a policy approach in both theory and application, two key areas of water fluoridation policy in the United States, the formulation and implementation of these policy efforts. To fully understand effectiveness at the implementation stage, research and clarification on the process of the formulation stage is important. This research contends that a more engaged formulation process that includes both water managers at the local level and agency experts at the state level are critical to policy effectiveness. Additionally, to understand whether the policy has been implemented and met, statistical analyses of water system reporting across the United States were performed. One of the key reporting and evaluation systems used in water fluoridation is the Water Fluoridation Reporting System (WFRS). One ambiguous part of this research is whether self-reporting related to meeting the recommendation is consistent with testing done for Consumer Confidence Reports (CCR). This is an area of future research.

Water fluoridation policy at the local level is a small part of water delivery processes but has large implications for natural resource and health management in the United States. It has become a contentious policy in the United States throughout its history, with some pointing to its incredible health benefits while others focusing on its potential negative outcomes. This project has a total of six chapters each highlighting a key area related to the identified research question.

There are six chapters in this study. Chapter one gives a brief glimpse into the history of water fluoridation and its recognition of achievement in public health. This chapter introduces the research problem, research question, and research significance. Additionally, it outlines the research endeavor.

Chapter two uses history and case law to set the policy background for the research endeavor. The history of naturally occurring fluoride in water is documented, including the initial discovery which led to the experimental use of fluoride to promote dental health. Additionally, as water fluoridation practice became the standard in this country cases emerged challenging the legality of this practice.

Next is a review of the literature used in making the policy recommendation by the Federal Panel on Community Water Fluoridation. The literature was classified by the researcher and then reviewed by type. Some pieces could arguably represent more than one type, however, classifying them assists in organizing the literature review.

Actors and various theoretical and policy analysis tools were used in chapter four in order to understand the policy history, along with clarification of the policy actors and their respective roles in engaging with the policy at different levels of governance. Describing the classes of actors and using exchange theory explores the roles of various policy actors in this policy environment. This further allows for theoretical framework development that explains the policy and potentially predicts future policy decision-making by policy elites.

Chapter five identifies the methodology used in the research study and presents findings as well as analysis of those findings. This research uses a mixed methods approach to explore the research question. Quantitative analysis of water system fluoride reporting was used to understand local efforts of reaching the policy recommendation. In addition, qualitative analysis, using a survey instrument, served to structure exploration of potential areas of attention or concern.

Finally, chapter six summarizes the study and generates discussion and future research opportunities. The summary provides a brief overview of questions raised by this study and provides some direction for future policy decision-making possibilities. This discussion focuses on policy realities and possible future direction of this policy area. Conclusions reinforce the status quo, that policy elites will be the final decision-making body based on the framework developed in this research.

Chapter 2: Policy History and Law

Policy History

For almost 70 years, water fluoridation policy has been growing and reaching more of the population; this appears to correspond to the depopulation of rural America and the increasing trend of urbanization. As of 2012 the CDC reports approximately three fourths of the American population is served by Community Water Systems (CWS) that fluoridate their water. According to the same summary statistics (Table 1), there are 52,734 CWS in this country with 18,502 providing fluoridated water. OF these 18,502 CWS, 6,342 CWS met the optimal fluoridation level in 2012. Further, the CDC reports that approximately 3.5% of the U.S. population has a water source with naturally occurring fluoride at or above optimal levels (Table 1). The optimal fluoridation level in 2012 remained 0.7 mg/L – 1.2 mg/L even though the policy recommendation was under review at the time. These recommendations were developed over time as research and policy in water fluoridation evolved. This issue remains an important consideration in both drinking water and health policy. In health policy, community water fluoridation can prevent a litany of long-term health problems by improving Decayed Missing Fragmented Teeth (DMFT) rates at a reasonably low cost to the community. Drinking water policy remains a hot button issue in many areas, including water fluoridation, and major movement in water fluoridation policy has occurred within the last five years. In the United States, this policy is implemented with water utilities adding a chemical to drinking water in order to produce a particular dental and general health outcome that cuts across socioeconomic lines.

Table 1: 2012 CDC Water Fluoridation Reporting System Data

2012

These statistics were prepared using water system data reported by states to the CDC Water Fluoridation Reporting System as of December 31, 2012, and the US Census Bureau state population estimates for 2012.

National Water Fluoridation Statistics

Total US population, people[a]	313,914,040
US population on community water systems (CWS), people[b]	282,534,910
Total US population on fluoridated drinking water systems, people[b]	210,655,401
Percentage of US population receiving fluoridated water[c]	67.1%
Percentage of US population on CWS receiving fluoridated water[d]	74.6%
Total number of CWS in United States[b]	52,734
Number of CWS providing fluoridated water[b]	18,502
Number of CWS adjusting fluoride[b]	5,999
Number of CWS consecutive to systems with optimal fluoride levels[b]	6,342
Number of CWS with naturally occurring fluoride at or above optimal levels[b,e]	6,151
Population served by CWS with naturally occurring fluoride at or above optimal levels[b,e]	11,116,202

Water fluoridation policy in the United States has a long history but the critical portion of this history can be argued to originate from the period of the Great Depression. The Great Depression illustrated on a grand scale how the lives of Americans can be impacted by a global economic catastrophe. As a result, many policy areas added a layer of centralized federal measures to assure the protection of Americans from the ravages of economic failures in the future. One of these areas included both public health and preventative medicine to promote longevity and reduce severe long-term health problems. Additionally, dentistry emerged in the 20th century as a field primarily involved in preventative outcomes. Not only was it determined that high rates of decayed missing and filled teeth (DMFT) could result in mouth and gum disease, the interconnectedness of systemic bodily health and dental hygiene was identified.

Dental hygiene and preventative measures became identified methods in preventing many negative and costly long-term health outcomes.

The beginnings of what is now a well-established health outcome related policy began some 100 years ago in Colorado. In 1901, a young dental school graduate by the name of Dr. Frederick McKay opened a practice in Colorado Springs, Colorado. He discovered that many Colorado Springs natives had brown stains on their teeth and in some cases all of their teeth were covered with this brown stain. McKay began his research on this localized dental phenomenon by looking for literature on why local teeth would be so stained. Local anecdotal evidence blamed the stains on a wide array of causes including pork consumption, milk consumption, and high calcium water. McKay could find no evidence to support such claims and then began to generate interest locally to find the source of what came to be known as the Colorado Brown Stain. (Murray et al, 1996)

Eight years passed until McKay was able to convince a fellow researcher by the name of Black to study the phenomena with him in Colorado Springs. Black was at first skeptical of such a disorder that had been missed by dental literature, but once he came to Colorado Springs, he could no longer ignore the situation since it was highly prevalent in the community. The Colorado Springs Dental Society performed a study finding upwards of ninety percent of the local population with the dental disfigurement. Black and McKay studied the mottling of teeth for the next six years until the passing of Black. Black and McKay published their findings in *Dental Cosmos* over the course of several months in 1916 (Smith, 1916). Their findings pointed toward tooth development from childhood resulting in irreparable staining of permanent teeth for life. Additionally, though, there was a benefit to this staining; the teeth were highly resistant to decay. McKay developed a hypothesis related to some ingredient in the water supply that caused the mottling of the teeth (Murray et al, 1996).

This hypothesis remained unanswered for several years until the opportunity presented itself to study the effect in a small Idaho town that had just constructed a new community water supply pipe. In 1923, the parents of young children in the community of Oakley, ID noticed their children had developed brown stains on their teeth. After evaluating the water supply and finding nothing of concern, McKay advised the community to find a water source from a different location; the resulting switch reversed the mottling effect in the community. At this time, the Aluminum Company of America (ALCOA) entered the water fluoridation picture when local children in Arkansas developed the stain. The water supply was examined, but again, nothing suspicious could be found. Fortunately, the Chief Chemist for ALCOA, H. V. Churchill, decided to perform his own analysis of the water supply in Bauxite, AR using photospectrographic analysis; the results pointed to high levels of fluoride in the water supply. After replicating his results, Churchill wrote McKay and the two began to gather samples from the towns that had reported the brown staining. After gathering the samples, high levels of fluoride were indeed determined to be the cause of the brown stain in local water supplies. It was by this careful scientific method of formulating hypotheses, collecting data, and replicating the results that community water fluoridation emerged (Murray et al, 1996).

In the 1930s scientists at the Public Health Service (PHS) and the National Institute of Health (NIH) became interested in determining at what levels of fluoride fluorosis would occur. Henry Dean of the PHS, after studying the effects of fluoride on teeth, created his own classification system for mottled teeth which is now more commonly referred to as dental fluorosis. His classification system placed teeth into the following six categories: Questionable, Very Mild, Mild, Moderate, Moderately-Severe, and Severe (Dean, 1934). Once classification was defined in order to record data, the research question focusing on water-fluoride levels could proceed. With the aid of advanced chemical detection equipment the research led to the determination that water supply levels of zero parts per million up to one parts per million of fluoride showed no enamel fluorosis in most people and slight fluorosis in small percentages of the population (Murray et al, 1996). This understanding of the levels necessary to prevent fluorosis led to the next research questions, namely, whether artificially adding this chemical into drinking water would help fight tooth decay. The hypothesis would need to be tested and replicated in order to provide a scientific foundation to make a generalized public health recommendation.

The job of scientists was then to develop the optimal level of fluoride in water to produce the desired outcome of dental health, without undesirable side effects such as pitting, dental fluorosis, and skeletal fluorosis. In conjunction with the City Commission of Grand Rapids, Michigan and the Michigan Department of Public Health, PHS researchers found the first city to unanimously vote to artificially fluoridate its public water supply in order to prevent dental caries (scientific term for tooth decay or cavities) in its population in 1945 (Silk, 2014, Murray et al, 1996). Grand Rapids became the first city in the world to add fluoride to its public water supply (Murray et al, 1996). Over the next 15 years, researchers recorded and evaluated the population’s tooth decay rates among Grand Rapids’ school aged children (Murray et al, 1996). The results showed a 60% decrease in caries in Grand Rapids, MI. Initially, there was a control city, Muskegon, MI, but within five years it had withdrawn and began fluoridating its water (Murray et al, 1996). The science began to build regarding water fluoridation and outcomes related to tooth decay. While the Grand Rapids project was in progress, a complete and well-defined scientific research design was needed to compare results of fluoridated water supplies versus non-fluoridated water supplies. Trials were set up in Newburgh and Kingston, New York with an experiment town and a control town. Newburgh, NY showed decidedly improved dental outcomes due to the fluoridated water while Kingston, NY did not (Ast, Finn, McCaffrey, 1950).

In the years that followed, research began to suggest optimal fluoridation levels, which accounted for regional water consumption differences. The level of optimal fluoridation was set to be between 0.7 mg/L – 1.2 mg/L to meet the optimal fluoridation level for artificially fluoridated drinking water systems (PHS, 1962, HHS, 2015). This policy established a range within which water utilities, whether they are municipally owned, private, or co-operatively owned, could determine their community's water fluoridation level. Again, this policy was intended for surface waters or ground waters that were naturally low in fluoride, with levels less than 0.3 mg/L being common surface water fluoride levels, to add fluoride to the water to bring it to a level to gain dental benefits (Meenakshi, 2006). With this federal recommendation, states and localities began to consider water fluoridation. By the end of the 1940s approximately 97 towns were artificially fluoridating their water sources, with the most water fluoridation programs occurring in towns in Wisconsin (McNeil, 1985).

The process for implementation at the local level is typical of federal environments of today and in the past. As an example, the federal government could not build low income housing in cities, however if the localities approved it, the government would help fund those initiatives with grants (Housing Act of 1937, Pub.L. 75–412, 50 Stat. 888). Likewise, in the case of water fluoridation, if states or local entities approved water fluoridation policy either in code or ordinance, the funding is available to apply for help implementing fluoride injectors into their water systems (PHHS block grant – Healthy People 2020). Additionally, many states have similar water fluoridation grants available for local communities to implement water fluoridation programs into local community water systems (Minnesota Department of Health, 2017, SCDHEC, 2017).

As this brief introduction illustrates, water fluoridation has been a decentralized policy implemented locally, but codified and regulated and/or advised by the state in some cases. While local and state relationships vary, constitutional foundations deem that local governments are creations of the state and are thus heavily influenced by this relationship. As regards water fluoridation policy, many communities passed policies into law by ordinance locally or are mandated by state code, but these policies have been heavily influenced by national research and policy recommendations. The current policy environment is one where the states are the owners of this policy area because of decisions by the United States Supreme Court refusing to hear water fluoridation cases. In questions surrounding state water fluoridation codes and regulations, decisions have been deferred to the lower courts (Wurzburg, 2013). This has resulted in a structure where states have varying policies surrounding water fluoridation and local governments can vary the level of fluoridation within national and state guidelines. This research will begin to explore this policy environment with both theoretical, quantitative, and qualitative methodological approaches.

As mentioned in the introduction, optimal fluoridation levels, recommended by the CDC, in 2012 were 0.7 mg/L – 1.2 mg/L. The population receiving naturally occurring fluoride in their water at or above recommended levels has been gradually increasing from 11,116,202 individuals in 2012 to 11,883,007 individuals in 2014 (Tables 1,2). However, water fluoridation policy was changing (HHS, 2015). In 2010 and 2011, a major policy change was made, with finality coming in early 2015 (HHS, 2015). This change was based on research indicating water fluoridation policy no longer needed to be regionally applied and that the level for optimal fluoridation according, to the national research council and agencies like the CDC within HHS, would become a standard 0.7 mg/L nationwide including Hawaii, and Alaska (HHS, 2015). Despite seeming like a minor change, this policy shift actually signaled a major policy change which eliminated the need for the local bureaucrats to self-identify the appropriate level of fluoride for their state, their county, their city. Instead this policy shift mandates one level, 0.7 mg/L, a policy recommendation which closes the door on a chapter in water fluoridation policy and opens the possibility for discussion of alternative models which could possibly be more suited to such a centralized policy recommendation.

Discussion of water fluoridation policy history is an important first step in assessing the policy landscape. Water fluoridation policy as implemented within the United States is additionally important to add depth to the background discussion. The next section focuses on fluoridation policy at the national and state level in the United States.

Table 2. 2014 CDC Water Fluoridation Reporting System Data

2014

These statistics were prepared using water system data reported by states to the CDC Water Fluoridation Reporting System as of December 31, 2014, and the U.S. Census Bureau state population estimates for July 2014. Revised July 2016.*

National Water Fluoridation Statistics

Total US population, persons[a]	318,857,056
US population on community water systems (CWS), persons[b]	284,099,832
Total US population on fluoridated drinking water systems, persons[b]	211,393,167
Percentage of US population receiving fluoridated water[c]	66.3%
Percentage of US population on CWS receiving fluoridated water[d]	74.4%
Number of CWS providing fluoridated water[b]	18,186
Number of CWS adjusting fluoride[b]	5,919
Number of CWS consecutive to systems with optimal fluoride levels[b]	6,015
Number of CWS with naturally occurring fluoride at or above optimal levels[b,e]	6,205
Population served by CWS with naturally occurring fluoride at or above optimal levels[b,e]	11,883,007

National and State Fluoridation Policy

Water fluoridation policy in this country has a long and well-documented history. From its beginnings with the discovery by local dentists in Colorado through its tests in several United States cities into its implementation nationally in hundreds of cities throughout the mid to late 20th century, water fluoridation is at the heart of contemporary systemic dental public health efforts in this country (ADA Oral Health Topics, 2017). Recently water fluoridation in the United States has shifted from following a more decentralized and regionally diverse policy, to a universal recommendation reflecting ongoing research and policy recommendations from nationally recognized research entities and national agencies charged with fluoridation policy recommendations. The historic, decentralized approach allowed for more policy customization by local entities, including the consideration of relevant variables like variance in air temperature and water consumption rates. The implications for this change signal a response to the growing concern over total fluoride exposure in this country and accounting for all points of exposure to prevent negative fluoridation side-effects (US Public Health Service Recommendation, 2015). Additionally, this policy shift is a reaction to calls to re-examine national fluoridation recommendations while also examining how community fluoridation is implemented.

Since 1979, the CDC has been the primary U.S. agency responsible for water fluoridation policy in the United States (CDC.gov, 1995). It is the federal agency, currently within the Department of Health and Human Services (DHHS) that has been tasked with advising, guiding, and recommending water fluoridation policy for public water system managers. Since there are no national regulations or laws that govern the use of water fluoridation, it has been left to the states to adopt administrative code if they choose to have water fluoridation programs at the local level or to allow local ordinances to be the driver of fluoridation policy. The Environmental Protection Agency (EPA), however, does regulate the maximum threshold for fluoride in water that is primarily naturally occurring, to which the primary threshold is 4 ppm or 4mg/L, with a secondary threshold of 2 ppm or 2mg/L for public water systems. The reason for these policy and agency differences is due to the purview of organizational responsibility and policy goals. The CDC has long been the U.S. agency whose primary concern is US health policy, while the EPA is the agency responsible for environmental law and regulation that may also improve and enhance human health or the natural environment. The differentiation of government agencies charged with oversight of specific federal areas can, at times, make it difficult to delineate policies which fall within the purview of several policy areas, such as health and environment.

Additionally, the Food and Drug Administration (FDA) is responsible for regulation and enforcement of consumable fluoride supplements, toothpastes, mouthwashes, and fluoridated bottled water (FDA Bottled Water Everywhere: Keeping it Safe, 2017, Code of Federal Regulations, 21CFR165.110, 2016). The complexities involved in interagency coordination and conflict has been established in public administration and policy literature (Ex: Kettl: Politics of the Administrative Process), and while it can be confusing to understand what oversight falls where within the federal context, the separation of responsibilities as it relates to water fluoridation regulation and recommendations seem to be effective.

The Safe Drinking Water Act of 1986 (SDWA, 1986) established the maximum contaminant level mentioned earlier which is meant to protect the public from overexposure to environmental pollutants and is under the purview of the EPA. Maximum contaminant levels (MCLs) are the levels regulated by the EPA of various environmental contaminants from industrial, agricultural, and natural sources within supplied drinking water. Secondary maximum contaminant levels are levels recommended by the EPA, but which are not mandatory. The SDWA is a significant policy in regulating natural fluoridation levels in drinking water, but does not relate to the policy change for the optimally fluoridated levels in drinking water. The MCL limits significant risks of skeletal fluorosis and severe overexposure, whereas the optimal fluoridation level promotes healthy teeth but also prevents cosmetic side-effects of excess fluoride. One can have serious health effects, the other cosmetic (EPA, Fluoride Q&A, 2015). While the two are considered separate due to desired policy outcomes by the different agencies which maintain advisory and regulatory policy control at the national level, both are concerned with environmental and health policy outcomes in drinking water. Water fluoridation programs are meant to have a public health policy outcome in which optimally fluoridated water is delivered through adding fluoride compounds to drinking water to meet national policy recommendations.

In 1995 and 1996 an amendment (S. 1316 SDWA Amendments of 1996, 1996) to the Safe Drinking Water Act required public water systems to publish annual Consumer Confidence Reports (CCR's). These reports were required to list source information for drinking water and contaminant levels in the water to improve transparency and demonstrate compliance with the national policy regulations of the Safe Drinking Water Act. They also include listing of water fluoridation levels for each water system in the United States and whether it meets compliance within the EPA requirements. The CCR water fluoride requirement for public water systems can be somewhat misleading as the CCR is meant to ensure compliance with MCLs, so in most cases public water systems delivering surface waters for consumption rarely approach the secondary MCL level of 2 mg/L. While there is no mandate for optimally fluoridated water, a separate line item for CCR's to meet the optimal water fluoridation level would be helpful to bring more water systems to the national recommendation.

Since there are no national regulations or laws regarding the practice of artificial community water fluoridation, the states have been the primary agent for first writing and passing legislation regarding the use or requirement of use of water fluoridation by public water systems. In some cases this effort has been left to the local municipalities, but the focus is first on the use of state codes and regulations. While each state is unique in how it regulates and provides guidance with water fluoridation, there are some commonalities across the states. As one example, South Carolina's code states that public water systems that add fluoride shall maintain water fluoride levels between 0.8 and 1.2 mg/L (Appendix A). This is an appropriate example of the challenge of meeting the new optimal fluoridation level as opposed to meeting a range of levels. First, challenges exist in changing the state codes. Second, without solid regulation mandating a certain fluoridation level, meeting the optimal fluoridation level will remain a significant challenge.

The Bureau charged with enforcing state regulations and encouraging the policy recommendation in South Carolina, the Department of Health of Environmental Control, released a memo following the national recommendation detailing these very challenges. Of importance for this project are the following: viewing of the national policy recommendation of 0.7 mg/L by CWS's as a ceiling, moving to a range of 0.49-0.69 mg/L (SCDHEC CW Fluoridation Plan, 2013-2018) which eliminates the possibility of reaching the optimal level, the state population served fluoridated drinking water remaining high, those receiving the recommended level dropping in 2015 and beyond, and whether additional planning for technical or educational training will be required to achieve the precise 0.7 mg/L adjusted level. The memo maintains the ability to achieve this recommendation but with significant time, understanding, and commitment by the local community water systems. The discussion of this commitment will be fleshed out more in chapter four regarding theoretical sociological and policy approaches including implementation and principal-agent concerns with the new policy recommendation and is significant in the qualitative driven approach to the methodology of this dissertation discussed in chapter five.

The list of states in Appendix B illustrates the decentralized nature of water fluoridation policy in the United States. Some states have administrative codes on the books that provide specific guidance on water fluoridation, while other states allow for local ordinances to guide water fluoridation policy. The majority of states have administrative codes on the books that specifically identify the state health agency as the primary compliance body. For local ordinances, many times the manager of the water utility is identified as the policy decision-maker with regard to fluoride levels in the water. In other communities, it is the mayor or other governing body that are charged with these decision-making powers. The water fluoridation reality in the United States is 43 states with codes/regulations directing water fluoridation practices, 7 states with no state code on the books relying on local ordinances, and territories such as the Virgin Islands and Puerto Rico having laws regarding water fluoridation levels. Does having an added layer of bureaucracy improve policy outcomes with the new water fluoridation recommendation? Future research could examine whether states that mandate or provide technical expertise and instruction in meeting the optimal fluoride level are more successful than states which rely on local ordinances/decision-making with no state guidance.

A brief example of the realities of decentralized implementation of water fluoridation could be summarized with an example of state regulations and complications of implementation at the local level and local decision-making and the policy recommendation as it relates to ordinances. As was discussed, there are real concerns for the state of South Carolina in implementing and achieving the water fluoridation policy recommendation as discussed in the SCDHEC Water Fluoridation plan 2013-2018. The primary driver in achieving the recommendation relied on local commitment and understanding of the recommendation. The issue at hand identified by this SCDHEC memo was not in delivering fluoride to the majority of the state population, but reaching the recommended level of 0.7 mg/L. In comparison, New

Mexico, one of the seven states that do not have a state code for water fluoridation, but allows for local water authority decision-making regarding water fluoridation (NMSA 1978, Section 72-1-10) had an interesting local reaction to the news of the pending final recommendation. In 2011, upon the release of the pending final recommendation for water fluoridation the Albuquerque water utility authority stopped adding fluoride to its local water (Albuquerque water utility authority, 2017, Albuquerque Bernalillo County Water Utility Authority town hall meeting minutes, 2014). In 2016, the water authority staff developed a plan to try and meet the recommendation, but it was not approved by the governing board (Albuquerque water utility authority, 2017, Albuquerque Bernalillo County Water Utility Authority town hall meeting minutes, 2014). For the time being, water fluoridation has ceased in Albuquerque, NM, with its water carrying a natural water fluoridation level of 0.4 mg/L (Albuquerque water utility authority, 2017, Albuquerque Bernalillo County Water Utility Authority town hall meeting minutes, 2014). While this does not imply that states and localities will be unable to meet the new recommendation, as is the case in policy recommendations and implementation at the local level, developing a recommendation is usually the easiest part of policy-making. Implementation, especially in a decentralized model, is the most challenging part of the policy process, usually escaping consideration with the policy elites working on the recommendation in a top-down approach such as this one (Sabatier, 1986).

There are several additional variations in this policy environment with Washington D.C. and US federal territories as examples of non-traditional water fluoridating entities that lie outside of the traditional federalist model in the United States. For example, Washington D.C., a federal city, purchases water from the U.S. Army Corps of Engineers for its residents (DC Water, 2017). This could potentially be the one anomaly in the case of water fluoridation residing with the states as the District is a federal city. As Washington D.C. is a home rule city and with the passing of DC Law 11-111 creating the DC Water and Sewer Authority (DC WASA) following Congressional review the case would seem comparable to other lawsuits brought against municipalities challenging legal authority to fluoridate drinking water (DC Water history, 2017). Being a federal city and purchasing fluoridated water from the U.S. Army Corps of Engineers can cause confusion in this policy area but is of little concern for this research other than adding nuance. Additionally, Puerto Rico and the U.S. Virgin Islands have laws in place to fluoridate drinking water despite being U.S. federal territories and not states. These examples of non-state/traditional localities decentralized nuances are used to demonstrate water fluoridation policy complexity in the United States with the significance being that United States citizens, no matter what federal reality they live in, are affected by this recommendation uniformly.

Scientifically, the new policy recommendation is a fixed 0.7 mg/L across the board no matter the climate or other related water or geologic variables. If implemented locally in all U.S. states, localities, and territories, the climates and geologies affected by this decision range from Alaska, 64.2008° N, 149.4937° W to Hawaii, 19.8968° N, 155.5828° W, to Maine, 45.2538° N, 69.4455° W, to Puerto Rico, 18.2208° N, 66.5901° W. It can be argued that this is an extremely large range from which to recommend such a policy that may need to include other local and regional variables into the decision of how much or whether to fluoridate. However, after the recommendations came in 2011 to publicly announce the shift from fluoridating water at 0.7 mg/L-1.2 mg/L to a flat 0.7 mg/L across the country, the move was applauded by health agencies (HHS, 2015), dental advocacy groups, (ADA website, 2015), and public health officials/representatives (Surgeon Gen perspectives, Public Health Reports, 2015). The decision was formally registered with the Federal Register on January 13, 2011 (FR Vol. 76, No. 9, 2011) alerting the public to the policy change.

Some of the leading research bodies in the country were tasked with undertaking this assessment of fluoride exposure and the risks involved in accounting for all known sources of fluoride exposure for the population. The National Research Council of the National Academy of Sciences published its findings in 2006, which recommended that due to the total exposure from, “pesticides, background food, air, toothpaste, and drinking water” total exposure of fluoride was in fact a health risk for several populations in the United States, primarily children and non-nursing infants (NRC, 2006). This research was primarily concerned with the EPA’s maximum standards and whether or not the maximum levels needed to be revised to reflect contemporary exposure levels. However, “Addressing questions of artificial fluoridation, economics, risk-benefit assessment, and water-treatment technology was not part of the committee’s charge” (NRC, 2006).

After additional research was completed for the study of overall fluoride exposure, including national surveys that demonstrated the increase in dental fluorosis, albeit very slightly, since the 1980’s (FR, 2011), the decision was made to formally announce the policy shift in 2011. This was reflected in final recommendations in 2015. Four years passed from the pending recommendation to review public comment and address any concerns by the HHS Federal Panel on Community Water Fluoridation. It allowed the panel to address valid concerns regarding the recommendation. In the final recommendation, it acknowledged concerns it explored, but, in the end, did not have any impact on the recommendation from 2011, making it final in 2015

(HHS Final Recommendation, 2015). While this is a significant recommendation, one that will undoubtedly be reflected in amendments to state and local codes, in the end it is only a recommendation. It will be up to the states, local governments and water districts to decide to follow these recommendations or not. Further, with this level of uncertainty this potentially leaves cosmetic overexposure to fluoride chemicals as a possibility across local communities if they do not bring down their levels to 0.7 mg/L or, even worse, underexposure to prevent tooth decay or stopping fluoridation completely in some places due to the complexities involved in meeting a recommended target instead of a range. In all likelihood, there will be fewer changes to codes and ordinances, a policy recommendation cascade effect in which water supply systems, receiving recommendations or training from state agencies, or professional engineers (PEs) attending conferences and continuing education seminars will follow this federal lead, and a tightening up of this policy variation but not completely eliminating levels both below and above the final policy recommendation.

Based on the numerous studies which were used to finalize the Federal Register notification, i.e.: (Kelly JE, 1975,Dye B, et al, 2007), (USDHHS, 2000; Newacheck PW et al, 2000), (McDonagh MS, et al, 2000a, McDonagh MS, et al, 2000b, Truman BI, et al, 2002, Griffin SO, et al, 2007), and others, the federal government supports the idea that community water fluoridation is still the most effective way to prevent dental caries and continues to remain safe. However, to remain cautious about exposure to fluorides, which can have severe dental and skeletal impacts among other side effects at high concentrations, it was best to signal a policy recommendation towards this concern by proposing fluoridation at the lower end of the earlier recommended policy spectrum of, 0.7 mg/L. While this recommendation is a scientific solution to total overexposure to fluorides for cosmetic purposes and to provide continued dental benefits, the implementation, as alluded to, will be a different matter.

Lindblom (1993) argued that the policy process in the Unites States is largely incremental in nature, which is arguably caused by the pluralist environment in which there are many sources of authority. While there is a justification for an incrementalist policy approach, as evidenced by the policy change remaining within the initial policy recommendation from 60+ years ago, 0.7 mg/L-1.2mg/L, and the resulting 0.7 mg/L recommendation, it is in other ways a departure from the decentralized nature inherent in the initial community water policy from long ago. The new policy reflects contemporary understandings of environment and exposure, including living conditions and water consumption patterns. No longer is it necessary to fluoridate higher in the north because it is colder on average and people drink less water, or fluoridate less in the south because it is hotter and people drink more water. Instead, based on evidence of total fluoride exposure, the recommended optimal fluoridation level for the entire country, continental and other is a flat 0.7 mg/L.

This research upholds that this policy approach is less incremental and may be best be described with application of another policy theory, which is the Advocacy Coalition Framework (ACF) Theory (Sabatier/Jenkins-Smith, 1993). In the ACF, policy subsystems are the primary drivers of policy change, including advocacy coalitions. As the introduction reveals, this was not a policy recommendation that went through politicians hands. This policy recommendation grew from recommendations made by nationally recognized policy elites/experts and the federal agencies involved in this policy area (HHS final recommendation, HHS Federal Panel on Community Water Fluoridation, 2015). The HHS Federal Panel on Community Water

Fluoridation consists of an interdepartmental and interagency panel of scientists assembled to review the collective science on water fluoridation and evaluate whether the standard range set in the 1960s needed to be revised (PHS, Fluoride Guidelines, 2015). While the belief systems are still quite evident and backed up by research in this area, the policy elites were forced to confront the only evidence that would allow them to make this recommendation, and that is recognized research performed by recognized policy experts. Based on Sabatier's concept of policy-oriented learning, (Sabatier, 1993) we can document the use of national surveys and studies used to assess relevant health and environmental impacts, with the end result being that the policy elites began to have the credible information necessary to make a policy change.

Questions still remain as to whether this policy recommendation is the correct one. While this departure from a range of 0.7 mg/L – 1.2 mg/L to a universal, flat 0.7 mg/L is an important step towards ensuring effective health and environmental policy in this area, it could be argued that the NRC and HHS did not lower it enough. The minimal level of 0.5 mg/L, which is commonly accepted as the lowest threshold to derive dental systemic benefit from fluoridated water (WHO, 2004) would be an appropriate policy recommendation as well since it achieves the policy outcome and would further reduce overexposure concerns. Perhaps that jump was deemed too large by the Federal Panel. Indeed large departures in policy can be difficult for framing purposes, and perhaps lowering the optimal recommended level to 0.7 mg/L was more of an incremental approach to scaling back water fluoridation levels in the United States. This policy change could be a small change which leads to another smaller change to the lower water fluoridation level, 0.5 mg/L, should the trends in dental fluorosis continue (Lindblom, 1993). Based on the accumulated evidence, this was a prudent and scientifically based policy recommendation at this time in the policy's history. Given the documented increases in fluoridation levels across the population, the research must continue to assess whether the optimal fluoridation level needs to be continually reassessed, but for now, the majority of scientists and policymakers believe the appropriate policy change has been made. Time will tell if states and localities respond to this policy recommendation and how it manifests.

With some discussion on the state of water fluoridation policy in the United States, it is prudent to discuss water fluoridation as it relates to its legal foundation. Water fluoridation case law is as important, if not more important than the policy history and implemented reality in this country as it solidifies water fluoridation as residing with the states. It could be argued that water fluoridation case law not only defines fluoridation policy in this country, but also determines its path moving forward.

Policy and Law

From a policy perspective, there is still an overwhelming amount of research in favor of fluoride use. In the United States the majority of states have water fluoridation programs of some kind and while water fluoridation is not mandatory, it is recommended by the Federal Panel on Community Water Fluoridation including many professional medical and dental advocacy groups including: the American Dental Association (ADA), the American Association of Pediatrics (AAP), the American Association of Public Health Dentistry (AAPHD), the American Medical Association (AMA), the American Public Health Association (APHA), the CDC, the Hispanic Dental Association (HAD), the National Dental Association (NDA), the National Institute of Dental and Craniofacial Research (NIDCR), the Parent Teachers Association (PTA), the U.S. Surgeon General, and the World Health Organization (WHO) (ADA, 2012). While compliance is decided at the state or local level, with overwhelming data favoring low fluoridation levels, it is highly practiced. Further, those influential in this policy-making arena remain entrenched by reduced DMFT rates and maintain community water fluoridation is still the most cost-effective method of delivering fluoride. This method of delivery has not come without its share of detractors who claim water fluoridation infringes on individual rights. Some of the case law from over the years sheds light on how some people perceive this policy.

While there is yet to be a study that effectively proves that fluoride should not be used in drinking water, there is still controversy with smaller advocacy groups over the proof of the early and continuing studies that demonstrate fluoride, at certain levels, is not detrimental to health and even promotes public health. Numerous court cases have ruled against those who are opposed to fluoridation practices. Some examples of court cases are:

- Froncek and others, Appellants, v. City of Milwaukee (1951),
- Alice Schuringa et al., Appellants, v. The City of Chicago (1964), and
- Carlton Hall, Appellant, v. Mayor Lester Bates, William H. Tuller, William C. Ouzts, R.E.L. Freeman, Hyman Rubin, Individually and collectively and as City Council of the City of Columbia, a municipal corporation, and Cary Burnett, City Manager (1966)

In the case of Froncek and others, Appellants, v. City of Milwaukee (1955) (Appendix C), several citizens of the City of Milwaukee attempted to prevent the City from treating its water with fluoridated products. The argument on behalf of the plaintiffs was that the city had overstepped its authority and taken upon itself a private health policy measure. Additionally, the injunction challenged the legality of the resolution as it related to other state and federal laws (Froncek v Milwaukee, 1955). In the end, the ruling was upheld and the city could legally fluoridate its waters in the interest of public health for the children specifically but also for its population implicitly.

In the case of Alice Schuringa et al., Appellants, v. The City of Chicago (1964) (Appendix C), several citizens of the City of Chicago had filed a complaint with Cook County, which received a favorable ruling to fluoridate its water supply. In this case, the plaintiffs could not prove beyond systemic harm resulting from community water fluoridation at such levels and the court found the public health measure to be sound and was reasonable to accomplish its policy aim. This is further confirmation that the courts are ruling in favor of the right of water municipalities and water districts, in the interest of public health, to implement water fluoridation programs. Even when constitutional concerns are raised, the courts find that water fluoridation, in the context of public health, does not violate constitutionally protected rights of individual citizens. This case attempted a hearing by the U.S. Supreme Court but was not granted certiorari, in that the Supreme Court argued it had no jurisdiction and the case of water fluoridation was not a federal issue.

In the case of Carlton Hall, Appellant, v. Mayor Lester Bates, William H. Tuller, William C. Ouzts, R.E.L. Freeman, Hyman Rubin, Individually and collectively and as City Council of the City of Columbia, a municipal corporation, and Cary Burnett, City Manager, again tried to file an injunction to prevent water fluoridation, this time, in Columbia, SC (Appendix C). The plaintiff's contention was that fluoridation infringed upon his individual liberty under South Carolina and United States constitutionally protected rights and was actually harmful for his arthritic condition. The court cited the growing case law relating to water fluoridation and refusal of the

Supreme Court to grant certiorari, ruling in favor of the state and city to continue fluoridating to protect public health.

In these cases (Appendix C), it becomes apparent that water fluoridation is an issue of public health, and that cities and water districts have an established right to water fluoridation programs. These programs are implemented at the city and county levels and have input from the citizenry as to whether or not they should be implemented. Some people may feel this violates their individual liberty, but as Tiebout and Hirschman described, people can "vote with their feet" (Hirschman, 1970, Tiebout, 1956). If someone does not like a policy or bundle of services, they can move to a place that does not have that policy or to a place where they can choose their bundle of services which more closely match their needs. There are major U.S. cities like Portland, OR, Albuquerque, NM, Spokane, WA, and Wichita, KS and other towns that do not have water fluoridation programs. Additionally, if someone is not served by a public water system, then they are generally not receiving artificially fluoridated water. This can be problematic for the policy as it is currently implemented as it potentially misses many rural citizens and those in cities that do not fluoridate because they do not receive the benefit the policy intends. While many would question whether someone would move over something like fluoridation policy, it still remains an option. It should also be a point of future research as to whether or not individuals should have the ability to opt out of fluoridation programs and if so, what that would look like from a community water system perspective. Further, one has to ask whether this is even feasible scientifically or efficient from a policy perspective. This could lead to other potential models, such as those in some European countries, which have eliminated water fluoridation in favor of other fluoridation practices that achieve a similar policy outcome.

As is demonstrated in the cases mentioned, precedent is set for the continued use of fluoridation across the U.S. and cities moving forward. The research used in the final policy recommendation found that the levels of exposure to fluoride based on current recommended levels for water fluoridation do not have a detrimental effect on children and young adults other than cosmetically. Forthcoming government studies and research will undoubtedly continue the assessment of dental health and fluoride exposure as it relates to these health outcomes. Questions, however, do remain as to how consistently the policy recommendation will be practiced at the local level. It is possible that these changes will slowly trickle down from state agencies or that local officials or continuing professional education will bring about or influence the recommended policy change. Furthermore, there is a significant population in this country, roughly one quarter, which are not reaping the benefits of community water fluoridation programs and others who are receiving overly fluoridated water. Ensuring that those who are at the frontlines of implementing this policy are receiving the signal to move in the policy direction intended by national policy actors and maintaining the health and safety of citizens is the most important consideration moving forward.

This chapter has set the stage for the policy environment as it relates to water fluoridation practices in this country. Relevant documentation and references to history, studies, regulation, and case law are important to contextualize the foundation of this policy area. Why does water fluoridation continue to be implemented in a decentralized way? As has been documented in this chapter, the historical beginning of this practice is firmly grounded in a decentralized model, but with a more centralized recommendation, would it be prudent to explore a more centralized approach to precise delivery to achieve the policy goal? The next chapter will focus on the relevant literature used to reach the final policy recommendation and the gap in the research which could be problematic for implementation of the recommendation.

Chapter 3: Review of the Literature

Introduction

The previous chapter outlined the history of this policy from its discovery, experimentation, the 1962 policy recommendation, its implementation, and the newest policy recommendation in 2015. Throughout the history of water fluoridation policy in this country and throughout the world, it has been a highly researched and, at times, contested policy area, especially in the United States. This chapter focuses on the contemporary literature used in making the policy recommendation by the U.S. DHHS Federal Panel on Community Water Fluoridation. The recommendation came as a result of considerations of water fluoridation effectiveness, fluoride sources, dental fluorosis trends, and water intake data (Public Health Reports, 2015).

Literature Review

There has been a great deal of research done on water fluoridation over the course of its history. Some of the most important research from the beginnings of fluoride research are related to how it can be effective in preventing dental caries and were detailed in the history chapter of this dissertation. For the newest recommendation, the DHHS panel on water fluoridation has taken into consideration some of the most influential historical research published on water fluoridation, in addition to more contemporary studies and government reports in making the 2015 final policy recommendation. There is considerable research in this area from around the world and inevitably not all studies of import to the field are included or incorporated into the final recommendation. This exclusion is not indicative of their research worth, but possibly did not add value to the policy consensus needed to make the recommendation. Likewise, this meta-analysis literature review highlights the same research papers and reports the Federal Panel used in making their recommendation but this is not to indicate other studies are not just as important in building the consensus of water fluoridation policy research. As this policy recommendation was finalized several years after its announcement, it is assumed that the Federal Panel would not have made such a recommendation without a well-rounded in-depth review of the most important and relevant reports and research published over the history of water fluoridation.

In order to make sense of the literature used in making the policy recommendation, there were primarily four types of references used by the Federal Panel that can be categorized as: historical or general publications, research on fluoridation trends, fluoridation-body interaction, and government data and reports. Some publications can be argued to crossover between types, however, for this literature review, each source will be placed where it is perceived to best fit. Specifically, this review of the literature will demonstrate the gap in research regarding implementation and stakeholder engagement of water professionals regarding meeting water fluoridation recommendations at the state and local level.

Historical and General

Historical and general literature as it relates to water fluoridation covers publications from the beginning of the water fluoridation period in the United States until the review performed by the 2011-2015 Federal Panel on Community Water Fluoridation. It includes water fluoridation literature relevant to understanding the effectiveness of water fluoridation programs generally, as well as general dentistry and oral development literature relevant to understanding tooth development or dental practices. This literature represents what would be needed to understand, at a general level, the need for water fluoridation.

Some literature that falls under the more general dental and oral variety can be found in the recommendation reference section (Federal Register, 2015). Tooth development and how tooth development relates to the tissues in the mouth is key in understanding how water fluoridation might benefit or hinder this development (Avery, 1987). In a similar vein, mapping of the mouth when healthy and when diseased is important to making recommendations on fluoride use in water (Massler et al, 1982, Lewis, Stout, 2010). General dental practices in American communities are also referenced for understanding basic field work in the United States and to help contextualize the setting for water fluoridation practice and outcomes (Burt, 2005). Additionally, tooth loss and the relation to fluoride products is important to understand for elderly patients or for those who were not exposed to proper dental hygiene during formation (Ismail et al, 1983). A general and broad understanding of oral health is key for developing effective water fluoridation policy recommendations.

Other more specific literature focusing on caries and caries prevention as it relates to water fluoridation were referenced in the panel's final recommendation as well. Notes on caries prevention and its cost-effectiveness from workshops were considered in the policy recommendation (Burt, 1989). Additionally, general research on fluoride and how it affects the caries process was also relevant (Koulourides, 1990, McClure, 1943). Decayed, Missing, and Filled Teeth (DMFT) rates of various age group demographics were also important in the initial policy recommendation and continue to be helpful for understanding the efficacy and continuing challenge of caries prevention in the United States ((Kelly, 1975, Kelly et al, 1973).

Results of United States studies of persons from ages one to seventy-four over a period of several years were critical to highlighting the broader nature of caries in and across the U.S. (Kelly et al, 1979). These studies were used to clarify the data on dental caries and their prevalence as it relates to certain age groups across the country. An additional component of this research explores how fluorides interact with caries prevalence and is another determining factor in water fluoridation policy recommendations.

Recommendations also considered variables related to water and climate conditions. These variables were important in the creation of the original policy and to the policy recommendation moving forward. Some of the influential literature in making the initial range recommendation was from the 1950s. Galagan was a key researcher of climate and how to determine a water fluoride recommendation based on climate and fluid consumption (Galagan, 1953, 1957, 1957). This knowledge of climate variation and fluid consumption as it related to determining the water fluoridation level locally was crucial in the early success of water fluoridation policy in this country and in determining the 1962 recommendation.

Fluoridation Trends

Effective monitoring of fluoridation trends to assess the impact of water fluoridation policy is important in building the science behind the practice in the United States and around the world. The various topical trends have included: consumption, oral trends in youth and adults, economic cost benefit analysis, and global trends and patterns. Together, these research areas help shape the contemporary landscape of water fluoridation practice and policy.

Over the decades, consumption trend analysis was critical in the revised policy recommendation. Heller et al (1999) followed water consumption rates during the middle 1990's which was some of the earliest work utilized to build consensus around this issue. This research found that water consumption no longer varied between regions of the country relating to temperature and therefore a water fluoridation range may no longer be necessary (Heller et al, 1999, Sohn et al, 2001). However, water intake among children through adolescence remained important for the final recommendation (Beltran-Aguilar et al, 2015), especially since school-age children's oral health is correlated with school performance and attendance (Detty et al, 2014, Jackson et al, 2011, Seirawan, 2012). To this end, socio-economic and health issues involved in this policy are important in addressing continuing dental health challenges for American children (Newacheck et al, 2000, Yeung, 2008). Related to this, overconsumption can be a health hazard and is important to consider as an additional equity consideration. Individuals who drink more than 2 liters of water per day were classified as overconsuming based on EPA calculations which could lead to fluoride overexposure. (NRC, 2006).

Oral trends are also important in determining a policy recommendation change for water fluoridation. Following oral health trends over the decades is a critical metric when determining a fluoridation policy recommendation. Not only are reductions in caries across age and other demographics important, but changes in fluorosis levels over time are an additional metric of importance (Dye et al, 2007, Griffin, 2007, Levy et al, 2010). Building the consensus that low level fluoride continues to have a significant correlation to caries prevention and reversal is important for continued water fluoridation practices (Featherstone, 1999). At the same time, understanding fluoride supplements in addition to water fluoridation and their impact on fluorosis is critical for ongoing research and evaluation (Ismail, Hasson, 2007). There is an ongoing tradeoff between mild fluorosis and caries prevention, and with the combination of water fluoridation and overall fluoride exposure, recommendations began to emerge in the 1990s to move the optimal recommendation down to 0.7 mg/L (Heller et al, 1997). Finding the right balance amongst all fluoride sources and the continued goals for positive oral and dental health outcomes while mitigating negative side effects is the direction water fluoridation policy continues to work towards (Truman et al, 2002).

Cost benefit analysis is one of the most important research areas for the continuation of water fluoridation in practice. Several key publications using this analysis highlight the ongoing value of community water fluoridation as a viable way to prevent poor dental outcomes. While cost dependent upon the size of the water system, it remains a lower cost additive for maintaining good oral health outcomes. While the cost on the technology and related additives may impact smaller and rural water systems disproportionately, when balanced against the overall benefit achieved from these efforts, the research remains positive and clear that the benefits of community water fluoridation outweigh the costs. Contemporary data trends on cost savings indicate that water fluoridation still has much to offer, especially in the context of rising dental and related health costs (Griffin et al, 2001). Related to the costs concerns, some studies specifically advocated for cost savings for water systems that do not fluoridate (O'Connell et al, 2005).

The Federal Panel on Community Water Fluoridation included trend analysis not only from the United States, but also from other parts of the world including: Australia, New Zealand, China, Scotland, and England. Similarly to the United States, Australia has been expanding water fluoridation practice over the years. There are similar reports from Australia on fluoridation guidelines (ARCPOH, 2006), fluoridation and the effects on dental caries (Slade et al, 2013), and costs and benefits with community water fluoridation (Campain et al, 2010, Cobiac, Vos, 2012). Understanding what has been done in other countries and the ability to learn from these policy changes and the potential implications for the United States is illustrated in fluoridation level reduction and caries trends of children in Hong Kong as the Chinese also reduced fluoride levels (Evans, Stamm, 1991, Lo et al, 1990). Additionally, in parts of China where naturally occurring fluoride levels are very high, studies were conducted on affected intelligence (Lu et al, 2000). There are similar naturally elevated fluoride water pockets in the United States such as those described in the history chapter and the brown staining of teeth. The relation to the recommendation is to reduce the potential for overexposure and more significant negative side effects. New Zealand researchers have also studied the effects of higher fluoride levels and their impact on intelligence and found no link between Community Water Fluoridation (CWF) programs and IQ and further went on to question previous studies who linked high fluoride levels and lowered IQ (Broadbent et al, 2014). English studies referenced in the recommendation were meta-analysis reviews and again supported the conclusion that CWF positives outweigh dental fluorosis negatives (McDonaugh et al, 2000, Parnell et al, 2009).

Body Chemical Interaction

Fluoride and interaction in the body is also an important component of water fluoridation policy. Many publications examine the chemical interaction of fluoride as it relates to various parts of the body. Getting the most benefit from the policy without doing harm internally is essential. As such it is important to understand in detail and over time how the body reacts to the chemical composition of the fluoride compounds used in CWF or those naturally occurring.

There are several publications from the ADA, one of the largest advocates of CWF that are related to chemical interaction with fluorides. There are several key references from the ADA directly tie-in to this policy recommendation. The first publication is general information on dental fluorosis, how it occurs and health implications for children (ADA Mouth Healthy, 2017). Additionally, the ADA provides research on the interaction of fluorides with the body and resulting fluorosis levels such as: topically applied dental varnishes and gels and infant formula (ADA, 2006, ADA, 2011, Pendrys et al, 1989, Pendrys et al, 1994, Wong et al, 2010). Other dental fluorosis literature reviewed by the Federal Panel include: tooth formation and the ongoing need for determining appropriate levels from all sources (Aoba, Fejerskov, 2002), the ability to possibly predict fluorosis in children by examining fluoride in fingernails (Buzalaf et al, 2012), fluorosis prevalence as it relates to tooth brushing and infant formula use (Osuji et al, 1988), and the dentist's role in reducing dental fluorosis (Pendrys, 1995).

More studies exist on significant reactions in the body from exposure to fluorides covering a range of health outcomes. Bone cancer studies are inconclusive. One study found a correlation in males with exposure to fluoride in drinking water since childhood but suggested further research to confirm or refute the results (Bassin et al, 2006). Since that study, a similar study in Great Britain had been conducted without finding a correlation with bone cancer (Blakey et al, 2014), which was supported by another study conducted by the National

Osteocarcoma Etiology Group (Kim et al, 2011). This research is supported by additional research demonstrating no correlation between fluoridated drinking water and bone cancer which could possibly arrive at a consensus of no correlation (Levy, Leclerc, 2012, Comber et al, 2011). Concerns related to chronic kidney disease and hip fracture due to water fluoridation were also not found to be significant (Ludlow et al, 2007, Näsman et al, 2013).

Finally, the relation of fluoride on the brain is one of the most studied components of fluoridation-body chemical reactions. First and foremost, fluoride is a neurotoxin (Grandjean, Landrigan, 2014), which is why fluoride levels and chemical use are extremely important to manage correctly (Crosby, 1969, Finney et al, 2006). High fluoride exposure has been linked to adverse effects of children's neurodevelopment (Choi et al, 2012) and IQ (Xiang et al, 2003, Zhao et al, 1996).These are to date some of the most negative potential outcomes of fluoride over exposure.

Government Data and Reporting

Government data and reporting is one of the most important components of this policy area especially as the policy moves to a uniform level for the United States. Ensuring the new recommendation is implemented and meeting policy objectives will be more important than ever in the coming years. Monitoring implementation and compliance of the new standard would be a potential indicator of success.

For the Federal Panel review, several health and environment government publications were incorporated into the policy recommendation decision-making process. As the primary federal agency in monitoring drinking water levels, the CDC is a major player in this policy area. The most prominent documents used included publications in the following areas:

- fluoride recommendations for dental caries prevention
- publication on achievements of public health heralding water fluoridation,
- oral health objectives for 2020,
- data on dental health and services,
- data from the WFRS i.e. statistics on water fluoridation coverage and self-reporting of compliance meeting the optimal level,
- lack of evidence regarding water intake and temperature,
- statistics regarding fluorosis in the United States,
- and infant formula recommendations as it relates to using fluoridated water (CDC, 1988, 1999, 2001, 2008, 2010, 2012, 2013, 2014)(Beltran-Aguilar et al, 2010).

As the CDC is under the larger DHHS, there are also publications from the HHS and one other sub-agency, the FDA, which were used in making the recommendation. HHS reports include the recommendation for the drinking water fluoridation change, publications on oral health, anticaries over-the-counter products, and those products as they relate to drinking water standards (HHS, 1962, 1980, 2000, 2010, 2011). The EPA is also heavily referenced in this review. The EPA documents included in the recommendation include documents on fluoride compounds for use in drinking water, fluoride exposure and sources involved, and examining fluoride dose levels to prevent cancerous effects (EPA, 2000, 2010, 2011).

Other governmental reports that were reviewed but did not fall specifically under the HHS or EPA umbrellas include other United States and foreign government reports. The Australian National Health and Medical Research Council (NHMRC) published a similar document to their American counterparts on the safety of CWF (NHMRC, 2007). A state workshop on identifying toxins and carcinogens and evaluating fluoride's role in bone cancer was reviewed (California OEHHA, 2011). A task force of professional health experts continued to tout community water fluoridation's effectiveness which was also important in the final recommendation (CPSTF, 2013). The National Institute of Health (NIH) also published findings on the oral health of children in the United States which ties into trends around caries and DMFT rates (NIDCR, 1989). In addition to national data and publications around the effective use of fluorides for the prevention of dental caries, the Federal Panel turned to international health organizations such as the WHO, Scientific Committee on Health and Environmental Risks (SCHER), and NSF International to round out the data and consensus regarding water fluoridation use and safety in preventing dental caries (NSF, 2013, WHO, 2002, SCHER, 2010).

Repeated studies have demonstrated through meta-analysis and peer-reviewed scientific evidence and consensus building that the practice of artificial water fluoridation is safe and is effective in the prevention of dental caries. Ongoing health concerns regarding overexposure and a better understanding of total exposure have led to the change from a recommended range of 0.7 mg/L (7ppm) – 1.2 mg/L (12ppm) to a fixed 0.7 mg/L (7ppm) in the United States. This was not a hastily-made recommendation, instead it was a recommendation made after decades of research, practice, and years of review before the final recommendation was announced.

This research is meant to address gaps relating to our understanding of the policy process of fluoridation and implementation to meet the new recommendation. This research further discusses the impressions from those on the front line in delivering the policy recommendation. In a decentralized system there are ongoing concerns that because many elements of the policy are left to states and localities, issues of implementation, monitoring, and enforcement may be less effective. The monitoring that occurs in this policy arena is directly with community water systems ideally fluoridating and meeting the optimal range (level). While a comment period was utilized before finalizing the recommendation, including feedback from water managers and associations, it appears that water managers had limited involvement in the decision except for this period. Their comments were noted, but the original recommendation decided upon before the comment period was finalized in 2015. In order to accomplish the goal of the policy recommendation, a fluid policy communication loop among all actors in the water fluoridation environment would be ideal to better understand perceptions and implementation realities of water fluoridation policy and practice.

The next chapter focuses on policy, sociology, and stakeholder theory and incorporates these theories into the context of water fluoridation policy in the United States. The use of theory will help describe actions and actors in this policy environment. Additionally, policy theory will be utilized to explain the lifecycle and interaction of those most heavily involved in water fluoridation policy and practice. Finally, stakeholder theory will bring context to the methodology of this research in engaging the local bureaucrats at the front lines of implementation and practice.

Chapter 4: Water Fluoridation Policy Theory

Chapter three reviewed the primary literature identified in making the new policy recommendation for the 0.7 mg/L water fluoridation level for the United States. The literature used in the decision-making process highlighted scientific and governmental studies used to build a scientific consensus regarding fluoride overexposure in the United States. While more cosmetically problematic than medically problematic at this time, it was deemed significant enough to move away from a decentralized recommendation to a centralized level for the entire United States. This shift is indeed an important modification to water fluoridation delivery and could potentially complicate implementation moving forward. To add context to the policy area and decision, this chapter is dedicated to theory as it applies to water fluoridation policy in the United States.

Theory is an important component in all research areas. It can be beneficial to help explain and describe various phenomena and in some cases help predict future outcomes. Policy study research has been working toward developing theories to help explain and predict future policy-making. This can be particularly challenging due to the many moving parts involved in the policy process (Sabatier, 1999). While this chapter will not likely move policy theory any closer to a grand theory, nor is its intent to add research in support of existing theories, several key policy theories have been used in order to help explain and describe water fluoridation policy in the context of the United States. Discussion will highlight the following policy theories: the Advocacy Coalition Framework (Sabatier, 1999), Multiple Streams (Kingdon, 1984), and Policy Diffusion (Berry and Berry, Sabatier, 1999). While there are other policy theories which have been researched and have gained attention, these particular theories seem best suited for explaining this particular research area.

Sociological theory also has much to bring to the table as Coleman's work on Exchange Theory and Purposive Action (Coleman, 1990) brings another perspective to this chapter. Water fluoridation policy decision-making can be viewed utilizing a sociological lens to contextualize the actors and the roles they play in this policy environment. While policy theory can be helpful especially in looking at the bigger picture process of water policy and delivery of the fluoridation recommendation, Coleman's rational choice/actor driven model of exchange and action can identify and describe individual actors and actions. The two theory areas can be seen as compliments to one another. Theories and frameworks in policy circles can focus on types of actors and how actors behave within a policy area and Coleman's theory accounts for this need (Schlager, Sabatier, 1999). Beyond that discussion, this chapter also describes and attempts to explain through description other theoretical values such as policy change due to collective action, institutions, and policy change (Schlager, Sabatier, 1999).

Additionally, policy options contextualized within policy theory have been used to transition this chapter to the methodology chapter that follows. Having a look at what other countries around the world do to meet the same policy objective helps contextualize and develop future policy alternatives if needed. Stakeholder engagement frameworks help set the stage for an important component of this research that follows in the methodology, results, and analysis chapter. Improving the policy process and understanding other potential policy options moving forward could be critical for the future success of fluoridation policy in this country.

Key Policy Actors: Exchange Theory and Purposive Action

Understanding the actors or classes of actors involved in water fluoridation policy at the community level can be achieved through the use of several lenses. Using a lens from a sociological perspective is discussed by Coleman in Chapter 2 of his book Foundations of Social Theory. Coleman's theory proposes that actors are purely self-interested and make decisions, in a vacuum, free of social norms and the contextualization of the environment in which human behavior exists. As Coleman so notes, he does not imply that self-interested behavior exists without the added context of norms. Coleman needs a starting point and makes the decision, based on sociological understanding, that if his theory were to begin with normative systems it would overlook the formation of these norms. In many ways, what Coleman is referring to is the theory of the social contract (Hobbes, 1651), which can be argued to be a precursor to the idea of the sociological perspective. It is in the Social Contract where we see self-interested behavior as dominant, but in order to maximize self-interest, there must be some formalized rules and governance structure to encourage and enforce a structured society. To be able to achieve such an environment, certain elements of self-interested behavior must be sacrificed.

While Coleman is not developing his theory without the added context of norms and their development, Coleman is able to develop his theory of actors without specifically needing to incorporate social norms that are generally understood or taken as a given when discussing rational actors within rational choice understandings and preferences (Bentham, 1789, 1907). In this way actor norms are set to understand actor decision-making behavior and Coleman creates an original position of sorts (Rawls, 1971). Coleman begins his theory with three types of action for an actor; the first action being primarily self-interested behavior over controllable resources, the second action is, according to Coleman, the most common type of action that accounts for social behavior and that consists of tradeoffs of minor interests for more control over major interests of the actor, and third is the complete transfer of control of resources that drives one's self-interest to another actor, who will better carry out the original actors self-interested behavior more effectively than he or she can under similar constraints (Coleman, 1998).

It is with this background that we begin to apply Coleman's theory on actors and action to water fluoridation policy. Understanding the actors involved, whether it be in the context of stakeholder engagement, authorizing environment, or Coleman's Structures of Action Theory is important in determining possible outcomes for decision-making, but to ignore the environment and norms would be a mistake. The current landscape of water fluoridation policy, what could be understood as the norms in the United States, was detailed in chapter one. This included the process of implementing water fluoridation programs, maintaining them, and responding to contemporary best practice recommendations from national policy experts. However, Coleman's theory indicates it is not necessary to specifically incorporate these norms into characterizing actors within this policy area as many of these norms are assumed and underlay the framework of this approach. In the United States, the policy environment/norms around governing structures and those responsible for enforcing those institutions can generally be understood within the context of American federalism. Without the understanding of American federalism, community level action and actors would be incomplete.

While the federalist landscape is described with more specificity in the policy environment context of historical and contemporary water fluoridation practice in chapter one, in order to set the stage for this chapter's theoretical additions of actors and policy theory, a more general description would be beneficial. Federalism, and for this discussion, American federalism, was designed with its powers divided amongst the national government and the states with each level having some powers independent of the other (Bond, Smith, 2010). The nation's fourth president, James Madison, who is credited with the design of the American system, to avoid factional rule and majoritarianism, created a harmonious system of mutual frustration (Bond, Smith, 2010). Since its creation, the federalist system has morphed through the ages of this country with varying labels to describe the interactions among levels of government, generally referred to as intergovernmental relations (IGR).

The federalist history follows varying timelines according to scholars, but one timeline describes it as such: Layer-cake federalism (1800's – 1930's), Marble-cake federalism (1930's – 1950's), Water taps (1940's-1960's), Flowering (1950's-1960's), Picket-fence federalism (1960's – 1970's), Façade federalism (1970's – 1980's), and De facto, telescope, or whiplash federalism (1980's – 1990's) (Shafritz, Hyde, 1992). Another set of time periods labels the periods of American federalism as such: Dual federalism (1836 – 1933), Cooperative federalism (1933 – 1961), Creative federalism (1961 – 1969), New Fiscal federalism (1969 – 1977), Partnership federalism (1977 – 1981), New regulatory federalism (1981 – 1989), Coercive federalism (1989 – 1993), Reinventing federalism (1993 – current) (Edwards, Lippucci, 1998). All these time periods, in which there is at times crossover or spillover between federalist phases, is just an attempt to describe the interactions among federalist levels at the time. It could be that America is still within a New federalism or Devolution Revolution federalist environment where powers shifted to the federal government are moved back to the states, but it will be to future IGR and federalism scholars to carve out and contextualize this time period in American federalism at a later date (Bond, Smith, 2010). It could be argued that by the end of George W. Bush's presidency in 2008, the new federalism period had ended (Bond, Smith, 2010).

So as not to digress too far from the subject at hand, developing Coleman's theory more fully within the context of water fluoridation policy and its actors with a more developed understanding of American federalism interaction is prudent to flesh the policy out. Additionally, federalism and understanding the context of mandates is important in this context, as water fluoridation policy-making has historically and is currently within a quasi-mandate federalism approach in that recommendations are made at a national level and then left to the states and locales to implement and enforce to meet policy objectives with little funding provided. The difference is now the range of fluoridation levels that were once left to the locales to calculate based on local conditions is now a flat level for the entire U.S. In using one of federalism and IGR's leading scholars, water fluoridation policy would resemble Deil Wright's overlapping authority model in which there is dispersed power in this policy area with modest and uncertain areas of autonomy and a high degree of interdependence in which the states and locales look to the federal or state levels for policy recommendation and then hopefully act accordingly (Wright, 1988, Agranoff and Radin, 2014). This could be argued by the inherent decentralized nature of this policy area in addition to the policy being a recommendation and not a federal regulation. Additionally, states and locales have the power to decide to implement or not. However, it is undeniable, that the data collection, analysis, and policy decision-making power lies in federal level hands.

Developing “classes of actors” in water fluoridation policy is another way of formulating a typology of sorts. This ideally allows for a better understanding of a group of actors who have a stake in the development and implementation of water fluoridation policy. In the community setting, the list of policy actors can be classified simply as the community water system (CWS) customers and the community water system itself. The CWS manipulates levels of chemicals in the water to meet or exceed governmental requirements for safe drinking water. In some cases, as is the case in environmental and health policy, some have their own requirements which go beyond what is minimally required by federal and state law. Customers expect drinking water to, at a minimum, meet the requirements for safe drinking water. However, water customers are only informed of water quality in detail on an annual basis, with the municipalities’ Consumer Confidence Report. This report describes the levels of certain chemical in the local drinking water, which is required by federal law. This policy is an effort to enhance transparency of federally applied and locally implemented health and safety measures.

These two primary community actors can be further classified as the customer and the provider. The customer, using Coleman’s theory would mostly fall into the category of action three (actions and transactions), in which full control of water resources used for consumption has been given to the community water system (Coleman, 1998). This is a significant action on behalf of the consumer as handing control over one’s water management is putting one’s life into another’s hands as water is required for human existence. Potentially the ultimate self-interest, self-preservation/life, being handed to another to ensure self-interest is maximized purposively and possibly in some cases without hesitation or complete understanding of the ramifications (Coleman, 1998). Many would assume that the majority of people have probably never looked at a CCR and the limit of their interaction with the water company is simply to activate or deactivate service, pay their water bill, or express frustration during times of outages or repairs; however, there are many who take an active role in monitoring community water reports.   For the majority of customers, control over their self-interest for clean and safe drinking water has been completely handed off to the water system. Large scale water systems, headed primarily by PE's, professional engineers, has a team of engineers and technicians responsible for manipulating the chemicals found in surface and ground waters to ensure that the water produced for the consumer meets drinking water standards.

Applying Coleman's theory, the water district, comprised of a professional engineering team, would most likely fall under action two (actions and transactions) (Coleman, 1998). Water district personnel, a field in which professional engineers dominate, are led by their self-interest in providing their community with drinkable water which meets or exceeds regulations of the federal and state government. In many ways, water districts are an extension of the government, often not specifically government controlled, but highly regulated and controlled if they are privately owned or cooperatively owned. In some cases municipalities own and operate the water utility, which can be an important resource for a community. However the organization is structured, the purpose of the organization is the same with these utilities carrying out a necessary, life-giving service for citizens, without explicitly being run by the federal or state government.

Again applying Coleman's theory, water utilities would most likely fall under action two as because they do have to give up some resource control in order to meet drinking water requirements, some of which are very costly. Action two in Coleman's section on actions and transactions is the action accounting for most social behavior in which, as is much possible, sole control over the resource will help realize the interest of the actor (Coleman, 1998). With the levels of regulation and monitoring involved in this area, the resource cannot be completely controlled by the actor. Water utilities still exert significant local control over resource management, but within social and institutional confines.

With the general setting of action and transaction among the provider and consumer more formally understood, classifying the actors within community water fluoridation policy can be more effectively explored. Certainly the most basic relationship between the consumer and the producer can be understood, but within water policy and policy in general there are always more actors in the policy environment. Beyond the basic customer who generally is not actively engaged in the policy environment, is the customer in the community, who could be considered a more engaged stakeholder due to their general interest in water fluoridation or participation due to the intersection of personal interest and professional experience. For example, the individual consumer who is a public health professional or civil engineer may be more engaged in this stakeholder community because they have academic and professional backgrounds that generate inherent interest in this issue.

Additional stakeholders include the Water Utility CEO, who represents the interests of the water utility and its employees, and has professional knowledge of water delivery systems and policy expertise in this regulatory arena, is focused on providing optimally fluoridated water, as recommended by the state's health agency and enforced by state law in conjunction with federal law (in most cases). The state health agency, which is an enforcement and advisory body, charged with meeting state law but also in advising water utilities in following national guidelines and best practices. The American Water Works Association and their state chapters, is a professional association for water utility professionals which helps determine best practices for water utilities and standardize delivery of fluoridated water is another key fluoridation policy actor. Certainly elected officials, both at the local level and at the state level, are also policy actors. Further, there are research think tanks such as The Environmental Working Group that conduct independent research to provide alternative research on specific areas of environmental and health policy such as water fluoridation. Many of these actors are involved more at the national level than as state or local actors. In a related vein, there are governmental agencies that affect national policy objectives that impact local level implementation. The key environmental agency is the EPA which regulates the primary and secondary thresholds for water fluoride levels, DHHS, and the CDC, which monitors and promotes optimally fluoridated water. Certainly it would be rare to see these national agencies involved locally except under extreme circumstances or crises, however, local level actors interact in a policy environment created and controlled by these larger national actors so it would be remiss to not consider these agencies as actors in the larger environment. Also, professional medical and dental associations, and their state based chapters, are primary actors both at the national, state, and local levels. Additionally, research bodies which are not strictly governmental, such as the National Research Council are major drivers of national policy recommendations in conjunction with medical and dental researchers in water fluoridation policy. As this extensive list of actors illustrates, community actors are a part of a much larger policy environment which constrains their ability to work independently at the local level. However, since this policy is implemented locally, it is best understood at a community level despite the larger state and national environment.

In terms of those stakeholders that actually are directly impacted by this policy environment, this area is not as complex as it might seem. Those who are most affected by water fluoridation policy as it is implemented or when the policy changes are those who are consumers of fluoridated water. As this dissertation is primarily focused on those who receive water fluoridated to a level that benefits their teeth, the estimate is approximately 75% of the population of the United States (2012 water fluoridation statistics, CDC). Those who implement water fluoridation and monitor its levels are the water utilities who act as the street level bureaucrats (Lipsky, 1980) and as the local agents for state principals in the state health agency they report to in the majority of states. It is in this context that we can extend our theoretical understanding of water fluoridation policy by attempting to apply it to the idea a quasi-Iron Triangle/Issue Network and relevant policy subsystems at the state level (Heclo, 1978).

Using this framework, state agencies enforce state regulations of water fluoridation levels and advise local water utilities on national policy recommendations in the majority of states. It is in this way that they serve as the agent who acts on behalf of the national policy principal (Jenkins-Smith, 1991) in a policy subsystem at the state level within the Iron Triangle/Issue Network. Since there are no national regulations involving optimally fluoridated water, the Iron Triangle/Issue Network concept cannot be applied perfectly and it becomes more of an Iron Duet/Issue Network (Yishai, 1992); with a clear relationship between National Agencies mentioned previously and the ADA and AMA lobbies in forming national policy objectives and recommendations. The reason this relationship is a mixture of Iron Triangles and Issue Networks is that in Iron Triangles, private interests come to bear based on a relationship between the private entity or business and the legislative and agency bodies. Issue Networks work less for private interests and more for public interests (Heclo, 1978), which may be a better approximation of the water fluoridation policy environment today. Additionally, since public processes have moved away from Iron Triangles of the mid-20th century to more open public processes, Issue Networks or variants thereof are a more contemporary explanation of how policy subsystems operate (Jenkins-Smith, 1991).

However, like Iron Triangles, the water fluoridation Issue Network can be almost impermeable, subjected to domination by policy experts and policy elites who determine who sits at the table to engage in major policy decision-making. Those not deemed as experts or those who oppose the dominant policy elite's closely held belief systems do not get to sit at the table to determine policy change and implementation. Therefore, despite the possibilities of local community level interactions and decision-making in water fluoridation, major policy-making power is wielded by policy elites (Jenkins-Smith, 1991), who in this case, are primarily nationally recognized research bodies who have close ties to dental and medical lobbies and the lobbies themselves at both the national and state levels. Within this gray area between older rigid iron triangle-like relationships and more contemporary policy practices such as Issue Networks lies water fluoridation policy.

As much as the state health agencies could be considered part of the policy elite, in the end, they bow to national agency policy recommendations (DHHS, 2015) which are primarily influenced by work performed by the Water Fluoridation Panel as discussed in chapter one. The CDC primarily controls the monitoring of state level data which is aggregated in data bases nationally for those states that participate (Water Fluoridation Reporting System). Some state health agencies perform independent research to understand if the policy objective is met through the current national recommendations (SCDHEC, 2013-2018). Control of the policy and monitoring of its implementation is held tightly at the national level, while implementation and meeting policy objectives is delegated to the state level and then to the local level, or in some cases directly to the local level; mimicking many current policy environments. While water fluoridation policy is being made at the national level, little resources or funding are provided to the state or local levels to fulfill these policy goals with the exception of some grant funding to implement community water fluoridation programs (SCDHEC, 2017). In summary, the state grant programs act as a middle agency to provide monetary assistance from the CDC to implement water fluoridation at the local level for eligible systems (SCDHEC, 2017). While it could be beneficial for the policy as a whole, state agencies would most likely not be considered part of the policy elite, but as more of a cog in the wheel of the water fluoridation policy subsystems and actors machine.

While the state agencies would be considered a weaker version of a policy elite actor if at all, they are at times crucial in maintaining the status quo. When locales are deciding whether to cease water fluoridation programs, which according to one state agency is more likely now that the policy recommendation has been finalized (SCDHEC, 2013-2018), state agencies have taken on a greater role of advocating for the continuation of fluoridation programs in communities. One example of this is in the case of Dillon, SC and Aiken, SC in 2007-2008 (Community Water Fluoridation Campaign Summary: Aiken, SC 2013, SCDHEC, 2013-2018). These examples illustrate how local efforts of weaker coalitions are often dominated by more powerful coalitions in this subsystem/policy network which is consistent with the ACF discussed in greater detail later in the chapter (Sabatier, 1999). The cities of Dillon and Aiken were considering ending community water fluoridation. In the case of Dillon, it was at the request of water operators, the street level actors of this policy (Community Water Fluoridation Campaign Summary: Aiken, SC 2013, SCDHEC, 2013-2018). In the case of Aiken, it was in reaction to a protest letter from a citizen to the city council (Community Water Fluoridation Campaign Summary: Aiken, SC 2013, SCDHEC, 2013-2018). Upon learning of this potential policy change at the local level, which is entirely legal within the state of South Carolina, a "Fluoridation Strike Force" which was a task force assembled at the state level, "created to learn more on the issue as well as provide local dentists and dentist team members with the necessary information, tactics and skills to fight the issue." (Community Water Fluoridation Campaign Summary: Aiken, SC 2013, p.1). It utilized the resources of the ADA and participants included: "dentists, hygienists, a water plant manager, Fluoridation Coordinator from the Bureau of Water (DHEC), and Division of Oral Health Staff (DHEC)." (Community Water Fluoridation Campaign Summary: Aiken, SC 2013, p.1). The goal of the strike force and of training the listed participants was to "improve the communication skills of individuals who came into contact with the public, especially to prepare them to face anti-fluoridation movements in the future." (Community Water Fluoridation Campaign Summary: Aiken, SC 2013, p.1). As a strong coalition with access to resources, this coalition was able to dominate local, less-organized advocacy groups opposed to water fluoridation. The Strike Force was able to build a campaign using local dentists to sign a petition in support of fluoridation. Using facts from scientific studies at the disposal of the ADA and the Strike Force, the dentists and Strike Force were able to convince the City Council to vote in favor of continued water fluoridation. Further, SCDHEC has established that when problems arise in the future with local implementation of water fluoridation programs, the

South Carolina Dental Association (SCDA) will stand guard and be ready to mobilize and deploy the Strike Force when necessary (SCDHEC, 2013-2018).

In this circumstance of South Carolina and its state subsystem of policy actors, it is clear that resources and mobilization of advocacy groups were used to dominate the policy process and ensure the policy outcome at the local level. This further demonstrates the influence and power these particular actors wield. However, this policy environment varies around the country and other outcomes have been achieved in other communities. There are major metropolitan areas of the United States which have been able to self-determine their local policy on water fluoridation despite heavy lobbying and advocacy movements in favor of water fluoridation in those areas. Two of the largest areas that have been able to form local coalitions that were strong enough to fend off the more powerful pro-fluoridation advocates were in Wichita, KS and Portland, OR, both of which do not fluoridate their water despite heavy pressure from water fluoridation advocate groups. Some of the cities and their local rejection of this policy were detailed more in chapter one with the description of the policy environment. The possibility exists that these major metropolitan areas could still become water fluoridated cities in the future. This would, in part, depend on national or state level research on fluoridation exposure and effectiveness but is more likely dependent on local politics and who the elected officials are and their agendas (political culture) (Elazar, 1994). These two examples, of which there are more, of decentralized policy illustrate that the policy environment, while largely dictated by this hybrid Iron coalition/Issue Network, also uses other models with more local power and control over decision making.

A component of Coleman's theory of action and classes of actors in decision-making could possibly be applied once more when examining water systems and their interaction with the policy elites in this area (Coleman, 1998). Since this is a decentralized policy area, and water fluoridation must be implemented by local cities, towns, water districts, it is then up to the local government bodies or water utilities to decide and then notify the public on the decision to either fluoridate or not fluoridate. An application of Coleman's theory in this case could be the exchange between actors at the local and national level. In this case, it could be argued that the local water providers have given up some of their control to the national policy elites to formulate water fluoridation policy recommendations, if indeed the majority of water fluoridating communities follow the newest recommendation. In turn, the national policy researchers and panel on fluoridation has relinquished some of its control by continuing to keep the policy decentralized. As there is no regulation to enforce this recommendation, the exchange of control must be clear between the actors involved for the policy to be a successful one. With the shift of the decision-making within a range left to the local level to a uniform 0.7 mg/L nationally, it will be interesting to see if the actors can continue maximizing their own interests in this current arrangement, or if a different direction needs to be taken in regard to method of policy implementation should the recommendation not be met or if more cities/states exit from the policy.

Structures of Social Action

Using Coleman's map of structures of social action (Figure 1, Table 3), what can be said of fluoridation policy? In Coleman's structures of action section, he begins the structure with an all-encompassing area which is purposive action (Coleman, 1998). Purposive action, as mentioned earlier, is purely an expression of self-interested behavior. Within this area are two major circles, one for transfer of rights of resources and another circle for events with consequences for many (Coleman, 1998). Focusing on the circle of events with consequences for many, he argues that this is, “the class of phenomena that gives rise to collective decisions and to the formation of corporate actors to carry out combined action.” (Coleman, p.37, 1998) identified as region 11 within said area. This appears to fit well within the context of water fluoridation policy. While Coleman’s argument seems localized to corporate actors, it could be argued that a professional engineer managing a water utility could represent a corporate actor or actors. Water utilities determine the level of fluoride and the type of fluoride used in their water system. This illustrates a level of control and decision making relevant for a corporate actor.

Figure 1. Structures of Social Action (Coleman, 1998)

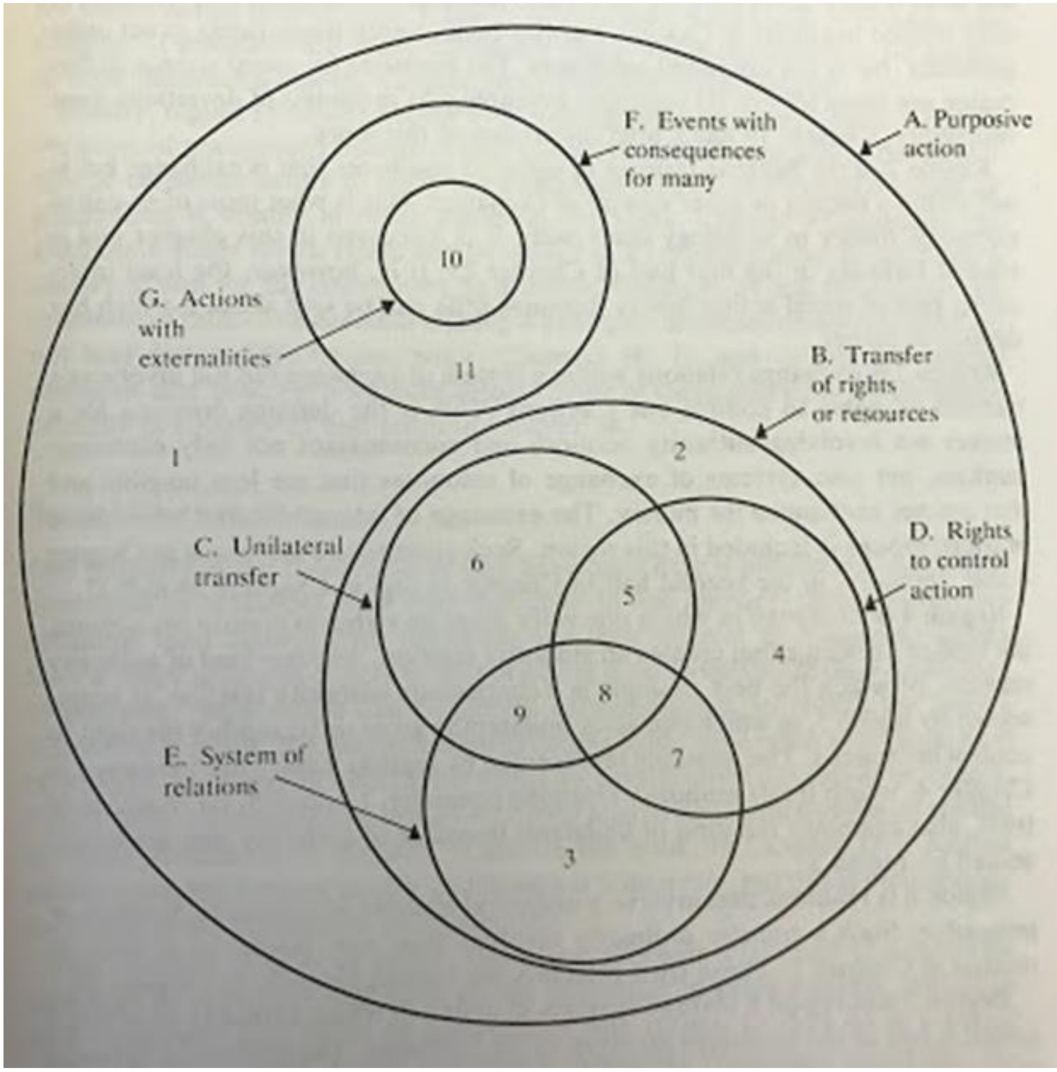


Table 3. Legend for Coleman's Map of Social Action (Coleman, 1998)

1. Private actions 2. Exchange relations 3. Market 4. Disjoint authority relations 5. Conjoint authority relations 6. Relations of trust	7. Disjoint authority systems 8. Conjoint authority systems 9. Systems of trust, collective behavior 10. Norm-generating structures 11. Collective-decision structures

The formulation of water fluoridation policy recommendations would also fall within collective decision-making (region 11, figure 1). Water utilities and state health agencies surrender their right to individual action in formulating local and state policy in regards to setting fluoridation levels to the larger body of national researchers and policy decision-makers should they follow the recommendation. This application fits within Coleman's theory; as to allow for collective decision-making it must be in the interest of the actor. In this case, the actors implementing the recommendation have already agreed, knowingly or not, that following the recommendation or allowing the decision to be made in the first place, was in their own self-interest.

For those states that opt out of the water fluoridation reporting system (WFRS) or are artificially fluoridating their water supply, while they have not rebuked the collective decision-making of the water fluoridation panel, they have chosen to reject the recommendation or policy in general, exiting the relationship of action/actors in this policy area. This could be for many reasons, but within the context of Coleman's theory, it appears to be because it does not maximize their interests to follow the recommendation or policy itself. The application of Coleman's region 10 within region 11 which is norm-generating structures (Figure 1, Table 3) could be argued in this case because as a result of collective decision-making, it could generate norms, arguably, how the majority of the United States and the actors at all levels behave with regards to community water fluoridation practice.

The relationship of the consumer and the supplier, on the other hand, could be argued to lie outside of this theory as humans need water to live and the choice among water provision is usually not an option. If the self-interested choice exists to wish to opt out of community water fluoridation practice by the consumer, he or she has limited options. Or it could also be argued that, as water is essential to human life, and as described initially in the action structure, in order to have access to water i.e. self-interested behavior, one is forced to allow collective decision-making of water providers to rule in exchange for potable water.

The concept of opting out could be further explained using another theory, that individuals have a right to vote with their feet (Tiebout, 1956). In theory, given Tiebout's assumptions, consumers could move to a city or state that does not practice water fluoridation. In reality, it could possibly be argued that water consumers have limited, if any, choice in their water provider not to mention the ability to move freely, because in most, if not all cases, there is a monopoly over water provision within a given area. Additionally, in some states, as mentioned in chapter one, practicing water fluoridation is required by state law. It could also be argued that despite the best intentions of water utilities and the federal government to provide transparency in water provision i.e. the Consumer Confidence Reports, some consumers are likely ill-informed as to the chemical composition of their water. This could result in incomplete consumer information negating Tiebout's theory.

The question then arises if region 10 and 11 (Figure 1, Table 3) are separated using Coleman's map, are they mutually exclusive from those actions contained in bubble B, the transfer of rights or resources? Considering that this trend continues into Coleman's section on the Social Optimum then it can be confirmed as such. While both exist within the same level of Coleman's map, the difference lies in collective decision-making versus individual action/exchange, so as such, they are exclusive. In the end, with the application of this theory, water provision, and, possibly more abstractly, water fluoridation, exists as a result of self-interested behavior and how that behavior manifests into collective action and decision-making such as community water fluoridation programs and how the actors operate within this structure at various levels.

In further refining the theoretical application of water fluoridation policy as it is currently implemented at the local level, water provision in general illustrates the complex relationships of public policy. A simple relation is defined by Coleman as "primordial social ties or relations of friendship" (Coleman, p.43, 1998). This simple relationship can build to be a more complex web of social interactions and relations of which water fluoridation policy does not represent. Water utilities would be more appropriately classified as complex relations, as relationship constructs based on the need for provision of a good or service. Coleman writes, "the economic goods on which modern life depends are products of the constructed social environment, which is based on complex relations," (p.44, 1998) which is certainly represented with a behavioral social decision to have public water providers, who in turn make the public health decision to apply water fluoridation. Water fluoridation policy is certainly determined by complex relations and not simple ones. Coleman notes government bureaus (agencies) are constructed social environments, of which all of the regulatory and advisory agencies at the state and federal level embody, including the research entities and advocacy/lobby groups which provide scientific research that supports the policy process.

Water Fluoridation Policy Process: Adaptive MS-ACF Policy Cycle

After spending considerable effort on defining the policy environment and the actors involved, the stage has been set to explain the policy process of water fluoridation further. As mentioned earlier, there are many frameworks for understanding the policy process.

Throughout the course of this research and trying to fit a policy framework to the broad arena of water fluoridation, it became apparent that no policy framework would perfectly apply to this area. This is an ongoing area of refinement needed in policy theory, as it is relatively an emerging research field and as mentioned, the moving parts make it difficult to design a predictive grand theory that can account for various policy areas having such specifically unique attributes.

For example, Multiple Streams (MS) (Kingdon, 1995) framework on agenda setting was used to interpret how water fluoridation policy came to the agenda many years ago. In the context of the original agenda setting event, in which it could be argued that the window of opportunity (Kingdon, 1995) for this policy was open for many years, the policy stream was the emerging scientific data regarding improved outcomes in the water fluoridation test cities, the problem stream was the DMFT/caries rates of teeth leading to other long-term health outcome problems across the United States, and the politics stream could be the national mood of the time and the action taken by test cities and state health agencies to implement (Kingdon, 1995). The problem with fully applying the MS framework was the inherent ambiguity required for the garbage can model of choice to be applied as this policy area is less ambiguous than most areas (Kingdon, 1995). While it is a complex set of interactions and behavior among actors, water fluoridation policy is less about MS, aside from the agenda setting stage, than it is an advocacy policy area. Additionally, the definition of policy entrepreneurs as described by Kingdon, was in some ways applicable to this area, but not closely tied to his original policy entrepreneurial approach for this framework (Kingdon, 1995).

As was mentioned, the application of MS was at times a stretch, and only furthered the potential understanding of the agenda setting component of water fluoridation policy, and incompletely due to the unique workings of this policy area and was obsolete after the policy began. In further attempting to explain this policy area with application of policy theory and frameworks, a modified version of the Advocacy Coalition Framework (ACF) was applied in order to help understand the dominant coalition, including the policy subsystems, policy actors, and policy elites involved in the area of water fluoridation. These actors and elites included the nationally recognized research bodies like the National Research Council, the Water Fluoridation Panel, ADA and AMA lobbies and other interest groups/Issue Networks (Heclo, 1978). The ACF was incomplete as only after the policy was adopted and implemented did the two coalitions begin to form. Once this took place, no longer did the policy need the multiple streams window, as the dominant coalition only required its policy elites to bring it back to the agenda stage once problems were identified.

The ACF points to policy-oriented learning in understanding the policy process (Sabatier, 1999). The recent national policy change is illustrative of this process as this shift occurred due to research at the national level using aggregated data. After the consensus of contemporary water fluoridation science began to develop, a better policy recommendation that reflected the changing water consumption patterns primarily due to air conditioning and more standardized environments less influenced by regional or state variations was necessary (HHS, 2015). Additionally, the ACF included shocks to the policy system in which the newest policy recommendation could be considered due to the change from locally determined levels of water fluoridation, to a nationally recommended set level of 0.7 mg/L. Again, these are the components of the policy area that the ACF can assist in explaining.

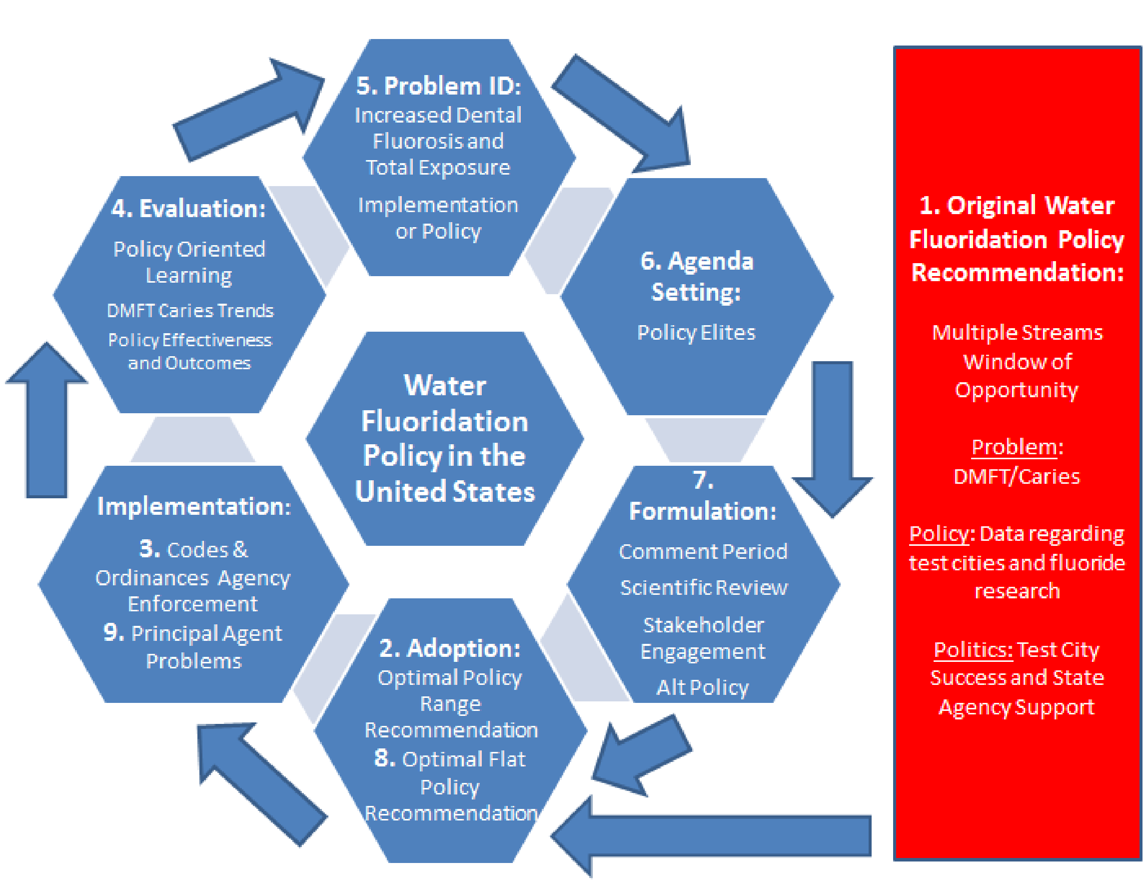
What we find is that the policy area is able to be described in many ways using those policy process tools borrowed from MS and the ACF described above. However, the ACF is too broad to be applied to water fluoridation specifically and Multiple Streams was sufficient in helping describe how water fluoridation possibly made into onto the policy agenda, but did not take the research any further. The application of both the MS and ACF (Kingdon, 1995, Sabatier, 1999) and Issue Networks (Heclo, 1978) reveals those who hold the reins of water fluoridation policy hold them close. In addition, like Iron Triangles, only recognized policy experts or elites are invited to the table to make policy decisions and are guided by their shared belief systems and common goals (Sabatier, 1986). In this particular policy subsystem, the health advocacy groups maintain the decision-making power, with resources and scientific fact at their disposal. These groups have held the power to make policy changes since water fluoridation's inception. Even reputable independent research entities are not seen as credible sources of research, and only those who are identified as policy research experts, such as those from the fluoridation panel (HHS, 2015), are allowed to have major input on policy decision-making. At the state level in many states, an Issue Network of sorts between the legislators, health agency, and advocacy groups is well developed. Even with this established network, there are still some opportunities for local variation in adoption and implementation of water fluoridation. The elites control the development and changes to the policy, but as it is a decentralized policy, local cities are still left to decide whether or not to fluoridate. Whether or not they are strictly left to make this decision on their own without the Issue Networks interference can be argued.

The best application may be a synthesis of components of Multiple Streams and the Advocacy Coalition Frameworks. To this end, MS and the ACF have been melded into a policy framework that also demonstrates a hybrid of policy process heuristic and adaptive management process to demonstrate the policy stages (Gunderson, 1999; Allen et al, 2011). The adaptive management cycle is: define the problem, identify objectives, formulate evaluation criteria, estimate outcomes, evaluate trade-offs, decide, implement, monitor, evaluate, adjust and then back to defining the problem (Gunderson, 1999; Allen et al, 2011). The policy stages/cycle heuristic is a more simplified version with problem identification and agenda setting, formulation, adoption, implementation, and evaluation (Anderson, 2003). Dominance by the policy elites/dominant coalition makes this adaptive model more appropriate for this policy area and less ACF-like due to policy change occurring without coalition power shifting but instead through policy oriented evaluation and adjustments.

The Adaptive MS-ACF Policy Cycle (Figure 2) illustrated the policy frameworks within the context of this particular policy niche in addition to showing the cyclical nature of water fluoridation policy which has now undergone one cycle in its history. Beginning with the red rectangular box (1. Original Recommendation, Figure 2) in the Adaptive MS-ACF policy cycle, the MS agenda portion of the framework initiates this policy's lifecycle and moves into the adoption stage. The policy recommended range was adopted in 1962 by the Public Health Service (PHS) (2. Adoption, Figure 2), based on trials in experiment and control cities, and then moved into the implementation stage (3. Implementation, Figure 2). At that point, the process of implementation by states and locales began shaping the decentralized policy landscape to the policy reality of today. Through scientific data analysis and evaluation processes (4. Evaluation,

Figure 2) explained in previous chapters a problem was identified, increasing dental fluorosis levels (5. Problem ID, Figure 2). This problem combined with data building on overall exposure led to water fluoridation policy coming back to the agenda (6. Agenda Setting, Figure 2) with the dominant coalition of policy elites formulating alternatives (7. Formulation, Figure 2) and coming up with a new recommendation. After the comment and review period, the new policy was finalized and adopted (8. Adoption, Figure 2) and is now in the implementation stage again (9. Principal Agent Problems, Figure 2). A new evaluation stage is not necessarily waiting for implementation of the policy recommendation, but it will be some time before evaluation data can demonstrate if there is a problem with implementation and whether that is a policy problem or an implementation problem. If there is a problem in the future, the policy elites could put water fluoridation back on the agenda and analyze the problem as a policy or implementation problem determining the future direction of water fluoridation policy.

Figure 2: Adaptive MS-ACF Policy Cycle (Walker Framework)©



The research question is not focused on how the policy change had been made within the policy process, which is crucial for understanding water fluoridation policy subsystem actors and policy elites, but is focused on the major policy recommendation and the opportunities and challenges in implementation of a toothless national policy recommendation at the local level. It is "toothless" in the sense that states are still in control of the policy despite the shift towards a more centralized policy objective and that the national policy is just a recommendation with little to no enforcement of the policy from the federal government. The primary research is then focused on the formulation and implementation stages with stakeholder engagement and implementation data to support future research to understand effectiveness and perhaps missed opportunities or future formulation possibilities. These two areas of analysis were critical according to Sabatier and Mazmanian (1984) as policy implementation is not a static stage, but part of an ongoing cycle of formulation, implementation, and reformulation. From a theoretical perspective, if these objectives cannot be realized as the policy is currently implemented, what are the opportunities for other policy models and how does this impact the policy process?

Implementation: Principal-Agent Theory

Principal-agent theory provides another theoretical application from which to explore this issue. This theoretical lens grew out of economics (Moe, 1984) and, at a later date, sociology and political science began to find the theory useful and it has been used in the policy environment by Jenkins-Smith and others. Moe (1984) was able to build on economic principal agent research and apply it to bureaucratic organization. His description of the principal agent model is as follows, "the principal agent model is an analytic expression of the agency relationship, in which one party, the principal, considers entering into a contractual agreement with another, the agent, in the expectation that the agent will subsequently choose actions that produce outcomes desired by the principal" (Moe, p.756, 1984). Coleman (1986) used principal agent relationships in building his theory of action and brought this interpretation, "(principal-agent relationships) can ordinarily be seen as brought into existence through exchange processes in which one actor, as entrepreneur or principal, engages in a series of exchanges designed to bring about a coherent product, gaining through these exchanges the control of others' actions" (Coleman, p. 1325, 1986). Jenkins-Smith et al (1991) then brought principal agent relationships to policy subsystems and actors to explain elite beliefs. The researchers that all made attempts at applying principal agent relationships to their fields highlight the crossover appeal for application of this particular theory and demonstrate its usefulness in this research area (Jenkins-Smith et al, 1991). While less useful for theory building, principal-agent relationships are another tool which can help describe behavior among actors within a policy area and explore interaction among actors at all levels of the policy environment. It is this dynamic between the principal(s) and the agent(s) that can complicate and even hinder the implementation and practice of policy.

Within the context of water fluoridation, there are many layers of principal-agent relationships, which add complexity to the potential implementation of this policy change as it was intended. The first principal-agent relationship occurs between the National agencies charged with making water fluoridation policy recommendations and changes. It can be argued that the primary agency here is the CDC, within the DHHS. Based on research conducted by the CDC and semi-independent research entities like the National Research Council, the Federal Panel on Community Water Fluoridation and, in turn, the CDC made a policy shift based on several years of independent research. Further, as already explained, this recommendation was more of a mandated level than the earlier recommended range. The agent in this particular relationship is the state health agency in most states, which in South Carolina is the Department of Health and Environmental Control (DHEC). State agencies across the country began to signal the water utilities about the policy change. There are several ways the state agencies disseminate policy changes, through e-mail communications using listservs and through more directed policy planning such as South Carolina's Community Water Fluoridation Plan (DHEC, 2013-2018). As this example illustrates, with water fluoridation policy there are first and second or levels of principal-agent relationships;, the first between the national agencies and the state agencies, the second relationship is then between the state agencies and the local water utilities. This is not the case in every state, but is in the majority of states. Increased principal-agent complexity could be argued in states in which local cities or water systems self-determine whether they fluoridate or not as referenced in chapter one. The goal is that the policy message will be carried down through each set of relationships and implemented as intended. The major problem with these relationships is the weak policy enforceability. First and foremost, there is no federal law regarding optimal water fluoridation levels, merely EPA fluoride threshold levels which are 4ppm primary threshold and 2 ppm secondary threshold as referenced in chapter one. Thus it is up to the states to enforce and incentivize the water utilities to follow national policy recommendations.

Another problem with enforceability is when and how states plan on changing their administrative codes to reflect the recommended change. Some states, like Kentucky, have a law requiring water systems to fluoridate their water as a state mandated health policy. In the case of Kentucky, the law has been modified from its original version in 1994. As of September 16, 2015 the law was changed to mandate water systems modify their tolerance range under law to 0.6 mg/L – 1.2 mg/L, with an optimal concentration of 0.7 mg/L (902 KAR 115:010, Water Fluoridation for the protection of dental health, 2015). The law originally called for a range of 0.8 mg/L – 1.4 mg/L with no less than 0.9 mg/L based on climatological information in the finished water (902 KAR 115:010, 1994). This example again illustrates the inherent variability in the implementation of this policy. Even with the optimal range now to a fixed point, at least some states are going to recommend the optimal level, but keep the flexibility found in the original policy recommendation from long ago. Is this because of path dependency issues, principal-agent issues, or implementation challenges in meeting the optimal level? Whatever the case, there are sure to be challenges involved in meeting the recommendation as there is no federal hand to push the states into compliance and changing their already existing laws.

Key components of the principal-agent model are information asymmetry, shirking, and incentives among others. Given how water fluoridation policy has been implemented over the last 70 years, a major policy change like this could cause problems like these in the principal-agent relationship. The principal in the past has allowed the local agent to decide what the water fluoridation level will be and there has been greater flexibility built into water fluoride levels with the former policy recommendation. Now that policy has changed to a more rigid 0.7 mg/L or ppm, this may make successful implementation an ongoing challenge. Water utility CEO's and professional engineers (PE's) may feel this policy change is of concern as they may have better information about their water system and the needs of their constituency and the national research may not reflect all of the variables that they would take into consideration. Information asymmetry is a theoretical example of this idea when the agent has more specialized knowledge of the policy at the local level than the principal. Even if the state health agency is instructing them to comply and fluoridate at 0.7 mg/L there are little to no repercussions in not achieving that goal since state law still generally reflects the antiquated policy. While state agencies can monitor and enforce local utilities in mandated water fluoridation states, in states with no state law regarding policy and enforcement, the agencies take on more of an advisory role. This could lead state agencies to shirk their responsibility in enforcing and taking charge of this policy area as they may not have the tools or resources available to enforce and in some states do not have that responsibility assigned to their agency. The potential disconnect between principals and agents could be significant in the successful implementation of the policy recommendation in the United States.

An important question with any policy change is whether there are incentives to facilitate the policy shift. In this case, there is a need for local water utilities to respond to this shift with limited incentives and without complete enforceability to ensure compliance. In this way, a carrot and stick type of reward and punishment system could be applied. A carrot in this approach would be training, continuing education, and outreach by any principals (CDC) to their agents (states or locales) updating their codes and ordinances or adjusting fluoride levels. A stick would be enforcement citations or other punishment the agent would wish to avoid for failure to comply with codes and ordinances or failing to adjust fluoride levels. Unfortunately, this carrot and stick approach would most likely fall to the states, and as has been detailed, some states are more firm in their policies in this area than others, making variability across the United States all but assured.

Fluoridation Policy Implementation

So if the policy recommendation is facing possible implementation challenges, what might be the problem? Sabatier's (1986) work on bottom-up versus top-down research in implementation reviewed both methods and additional attempts at synthesizing the two. The discussion of Sabatier's ACF has already been put forth in the development of the Adaptive MS-ACF Policy Framework Cycle, which argues that until the policy had been adopted and implemented, more than one coalition did not exist. Additionally, the policy change did not occur as a result of a change in power among coalitions, but as a result of policy elites' identification of a new problem and data to evaluate and formulate policy options. Sabatier does evaluate another synthesis of top-down and bottom-up approach to implementation and that is Elmore's backward mapping and forward mapping concept of implementation (Sabatier, 1986). In this concept, forward mapping includes policy-makers understanding of policy instruments and resources available and the incentives needed for the targets of the policy (Sabatier, 1986). The need of understanding incentives is key in implementation which was potentially lost in this policy recommendation.

Pressman and Wildavsky described a similar implementation challenge where the authorizing environment was not fully understood by policy makers at the national level and, therefore, the local implementation did not match the policy as it was formulated and adopted (Pressman, Wildavsky, 1984). This scenario highlights the complexity of the relationship of street-level bureaucrats and state and federal agencies and further highlights the importance of understanding these principal-agent behaviors for understanding national policy changes that demand local implementation.

Pressman and Wildavsky created an illustrative table useful in understanding policy implementation outcomes. They developed their implementation table based within the context of Herbert Simon's preprogrammed world (Pressman, Wildavsky, 1984). The basic tenets of this table lie within two components of policy formulation, adoption, and implementation that Pressman and Wildavsky labelled the (policy) decision and the (policy) execution (Pressman, Wildavsky, 1984). Within these two policy components, there were two outcomes for each, good and bad (Pressman, Wildavsky, 1984, Table 4). If the (policy) decision was good and the (policy) execution was good, there was no implementation problem (Table 4).

If the (policy) decision was good and the (policy) execution was bad, then there was a problem with control (Table 4). If the (policy) decision was bad and the (policy) execution was good, then there was a problem with the policy (Table 4). Finally, if the (policy) decision was bad and the (policy) execution was bad, then, again, there was no problem (Table 4) (Pressman, Wildavsky, 1984).

Table 4: Implementation in a Preprogrammed World (Simon, Pressman, Wildavsky, 1984)

	Decision: Good	Decision: Bad
Execution: Good	1. No Problem (Too Good to be True)	3. The Policy Problem
Execution: Bad	2. The Control Problem	4. No Problem (Or: how two bads = one good)

By applying water fluoridation policy to this table (Table 4), it could reveal potential issues with the recommendation moving forward. If the policy recommendation is good and the implementation outcome is good, then there is no problem, which is potentially a realistic outcome in this case. It could very well be that the recommendation based on scientific evidence and with the structures already in place for implementing this policy could have a good implementation outcome. If the policy recommendation is good, and the execution is bad, then there is a problem with control. In this case, it could also very well be a realistic outcome. As was mentioned, there is little enforcement capability for this policy in the United States as a whole. Additionally, there are many water systems that do not choose to fluoridate. Without a control mechanism, such as in the case of Kentucky and other water fluoridation mandate states, there is little enforceability. If the policy recommendation is bad and the execution is good, then, again there is a policy problem. This would likely be the least likely problem in this policy area; that all water systems follow the recommendation, but the change was not effective in reducing fluorosis levels in the United States. Finally, what if both the policy recommendation decision and execution are bad? This could very well be an outcome as well in this area. Perhaps the recommendation did not go far enough and local water systems could not meet the recommendation. This seems like a less-likely scenario, but remains a possibility. So if the policy recommendation decision and execution policy problems of sections 2, 3, and 4 of the implementation table (Table 4) do occur, what are some policy alternatives and how would they look realistically in the United States in the context of policy theory?

Other Fluoridation Approaches and Policy Options

Once this major shift was made and a centralized policy objective was recommended for optimal water fluoridation, it opened the door for other nationally centralized approaches to fluoride policy which may be better suited to the current policy environment. The first approach taken by some European countries is salt fluoridation. Studies have been conducted internationally that demonstrate salt is applied among various socioeconomic groups alike and further, that fluoridating salt can also deliver similar policy outcomes (Schulte, 2005, Horowitz, 2000). Some European countries with initial water fluoridation programs, abandoned them to move to salt fluoridation (Marthaler, Pollack, 2005, ADA, 2005). The reason for the move from water fluoridation to salt fluoridation in Europe is for many reasons including, “technical, legal, financial, or political reasons” (ADA, 2005, p.54).

Berry and Berry’s Policy Diffusion model could possibly be applied to demonstrate how policy is adopted by other states/countries that are geographically similar and close in proximity

(Berry, Berry, Sabatier, 1999). If salt fluoridation models are more or equally as effective, what keeps the United States from following suit and implementing a national fluoride program using salt fluoridation? It has the potential to eliminate the principal-agent problems, allowing for one national agency to develop and approve the appropriate fluoridated salt level, which would eliminate water fluoridation variability. At the same time, people in cities who do not fluoridate could opt in and buy fluoridated salt, while people could also opt out and exit the fluoride relationship, sticking to toothpaste and other methods of delivery. One of the major flaws in the policy diffusion model is its ability to spread policy across large areas, such as the ocean which lies between the United States and Europe. The theory behind diffusion is that innovation and emulation by others relies on, "learning, competition, and public pressure" (Berry, Berry, Sabatier, 1999, p.175). It is also unlikely that the CDC or Water Fluoridation Panel would lead the way in policy innovation by moving toward salt fluoridation programs given the existing control and path dependent nature in the community water fluoridation environment. If implementation of the policy recommendation is not met to the satisfaction of policy elites, it could remain a viable policy alternative.

Another policy model is school milk fluoridation programs. Since fluoridation has been shown in replicated studies to have the most impact in infants to young adults this is a rational policy approach (ADA, 2005). There is an argument that fluoride exposure over one's entire life is important for continued dental health (Horowitz, 2000) which limits the likelihood of milk fluoridation programs ever gaining a foothold in the United States. This program would be more of a targeted intervention for the largest impact and would provide for exit opportunities. The

United States has not explored either of these policy options either and has shied away from looking at more centralized policy models consistent with the newest policy recommendation.

Stakeholder Engagement Theory

In the effort to gather research and stakeholder engagement before this policy change, this research upholds that stakeholder/authorizing environment feedback from local water utility managers was weak (HHS, 2015). It does not appear water utilities or water managers were consulted in the decision-making process until after the comment period began, which is an important consideration when this is the implementing environment (HHS, 2015). The street level bureaucrats who must implement the policy change with few or no incentives or enforcement could be more involved in the decision of whether to implement a uniform level or to narrow the range of water fluoridation levels. Within the context of the Adaptive MS-ACF framework, this future engagement would happen in the formulation stage of the adaptive process.

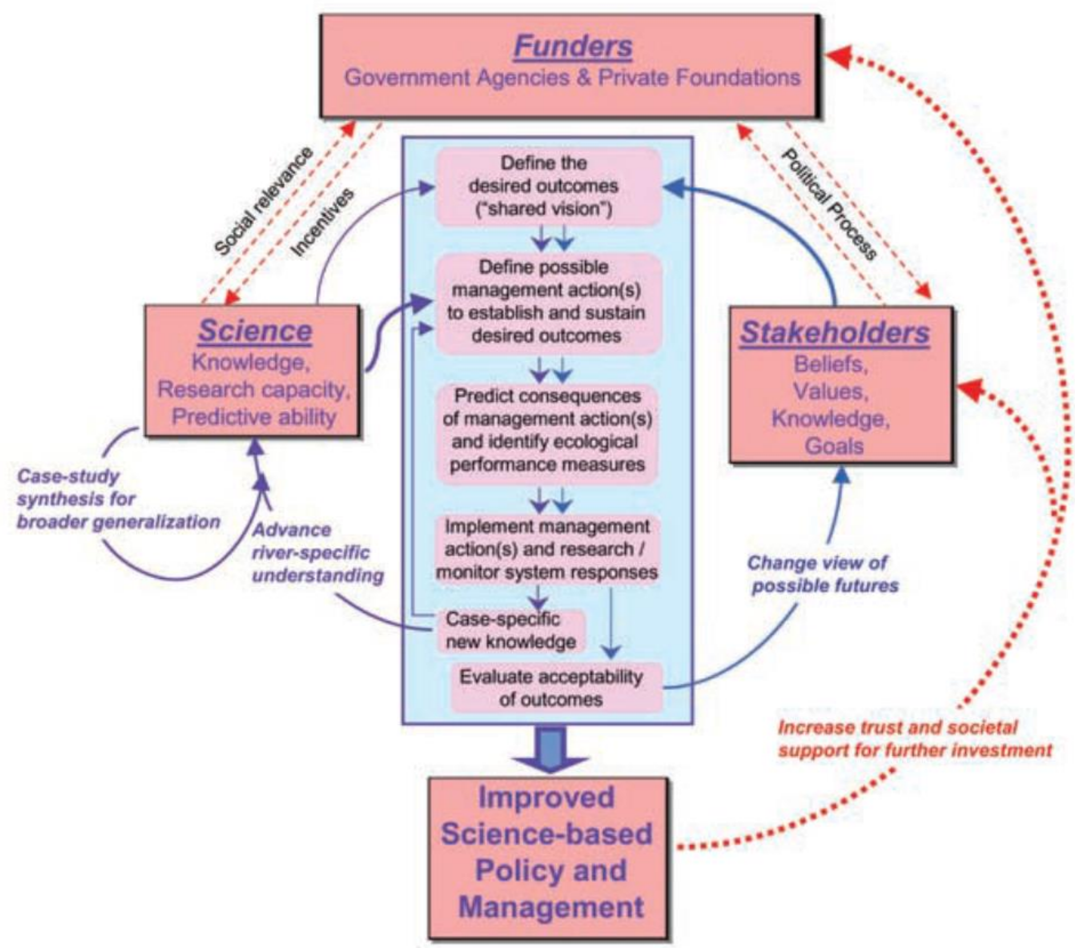
There has been significant research done over the past decade or more in stakeholder engagement practice and theory as policy decision-making has moved from a black box environment of iron triangles to a more participatory approach i.e. Issue Networks (Heclo, 1978, Sabatier, 2005). As the movement for more transparency in government processes has become more the norm, the policy elites who once sat behind closed doors to engage in policy decision-making processes must now engage stakeholders in order to encourage buy-in and ownership of the policy process and, in turn can expect improved implementation outcomes in theory (Sabatier, 2005). No longer should policy be an input - black box - output process with hopes of being successfully implemented at the local level. The problem as identified by Sabatier et al is the growing level of dissatisfaction with policy decision-making lying in the hands of policy experts (Sabatier, 2005). The new model of collaboration, which is more of a Hayekian bottom up approach instead of a handed down Keynesian approach in the context of water management, is very different from public hearings and comment periods (Sabatier, 2005). The value of a participatory approach to water management is it can resolve disagreement before the policy is implemented and may, “have greater legitimacy than traditional approaches that rely on the legal authority provided bureaucracies by legislatures.” (Sabatier et al, 2005, p.4) Koebele elaborates further and drives home this important concept of a participatory approach to water management, “since their emergence, collaborative governance processes have been hailed as the panacea for failures associated with traditional, top-down modes of governance” (Koebele, 2015, p.63).

The definition of a stakeholder has evolved, however, understanding who is a stakeholder in a policy area can be daunting. Sabatier et al define stakeholders as including, “policymakers, agency implementers, experts both within and outside government who participate in policymaking and policy implementation, private sector businesses that are economically affected by policies, members of the general public who are economically or otherwise affected by policies, and environmental interest groups that purport to represent nonhuman values, among other groups” (Sabatier, 2005, p.21). Cowie and Borrett define stakeholders as, “those responsible for, affected by, or expert in a particular issue or decision. People who hold multiple perspectives and other different kinds of knowledge about the issue, including operations managers, other experts, and sectors of the general public, are all potential participants” (Cowie, Borrett, 2005, p.473). Some of the useful takeaways for water fluoridation policy stakeholders who generally do not get a seat at the decision-making table until the comment period are: state health/environment agency officials, water managers, the general public, and water fluoridation interest groups (HHS, 2015).

In addition to defining stakeholder participants, deciding how those stakeholders participate is of equal importance. In the Integrated Urban Water Management framework, there are several questions surrounding stakeholder engagement which must be first understood in order to proceed in the participatory process: “participation by whom, in what, when, and to what end” (Cowie, Borrett, 2005, p.469). This can lengthen the planning process for policy elites not used to engaging with stakeholders in water fluoridation policy. Additionally, water fluoridation policy is a highly volatile policy area as touched on in chapter one and also alluded to in the final recommendation (HHS, 2015). Cowie and Borrett allude to stakeholder contention by saying, “stakeholders often come into these forums as ‘cooperative antagonists’” and that, “participants recognize their diverse interests and agree to work toward common ground, but expect themselves and other participants to be primarily concerned with their own interests” (Cowie, Borrett, 2005, pp 473-474). This could have been a deterrent for the panel on fluoridation to include stakeholders in the policy process until the comment period.

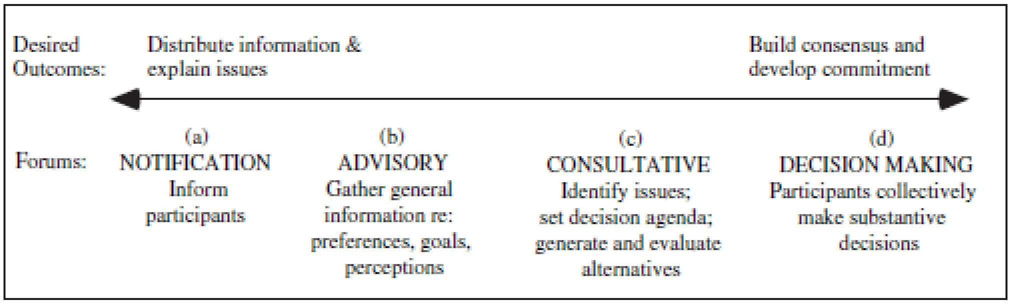
Knowing what makes up a stakeholder group in water fluoridation policy, who should be involved, and how is important in the stakeholder process. Additionally, what makes stakeholder engagement efforts successful? There is a diverse set of works on what constitutes successful stakeholder engagement in water policy processes. The Stakeholder Process for Improved Science-based Policy and Management (Figure 3) illustrates the complexities involved when a nexus between science, stakeholders, and funders occurs in water management (Poff et al, 2003). The feedback loops demonstrate how difficult "improving science-based policy and management" in water policy can be (Poff et al, 2003, p.300). This figure represents more of a collaborative model where the stakeholders have a large role in the development of water management policy decision-making.

Figure 3: Stakeholder Process for Improved Science-based Policy and Management (Poff et al, 2003)



Water fluoridation policy experts, after review of the scientific consensus in water fluoridation policy trends, decided to make their policy recommendation and then open the recommendation for a comment period. In many ways, this can be seen as a weak stakeholder engagement effort since many stakeholders were not involved in determining the strengths and weaknesses of the policy recommendation. At the same time, this most likely kept the policy process less contentious. According to the literature, this could potentially undermine the stakeholder process, which is yet to be seen. Using Cowie and Borrett's figure on stakeholder engagement (Figure 4), this process would likely be seen as a Notification or Advisory type of stakeholder process in which the fluoridation panel informs stakeholders as the policy recommendation is made (Notification) or gather general information re: preferences, goals, perceptions (Advisory) which is consistent with the comment period and evaluating comments (Cowie, Borrett, 2005). It would be difficult to argue that this process has been Consultative or Decision-Making in nature by the stakeholders (Figure 4, Cowie, Borrett, 2005). The timeline for the policy recommendation evaluation and final recommendation was several years which could have allowed for more stakeholder inclusion; however, whether or not stakeholder involvement would have affected the outcome is unknown. Gaddis et al suggest, "the extent to which the public or a representative stakeholder group can participate in water resources research and management is determined by the methods employed in engaging stakeholders, inclusion of diverse groups, group size, incorporation of local knowledge and expertise, and the time and funding available for the process to develop" (Gaddis et al, 2010, p. 1429).

Figure 4: Continuum of Authority for Participatory Decision-Making (Cowie, Borrett, 2005)



It is possible that the fluoridation panel did not have funding or expertise in engaging stakeholders in such a way, or perhaps would not be able to engage with diverse groups of stakeholders in a way that would seem representative of stakeholder groups. It would certainly have been a large undertaking to engage with stakeholders around the country. Perhaps a survey could have been worked out with the AWWA and sent to members nationally. There are always ways to improve stakeholder engagement methods within the scope of funding and time. In many ways this policy recommendation process for water fluoridation levels can be seen in both positive and negative ways according to the literature on successful participatory management stakeholder engagement efforts. Gaddis et al suggest stakeholder participants need to be, "involved with the stakeholder process at various stages, including model selection and development, data collection and integration, scenario development, interpretation of results, and development of policy alternatives" (Gaddis et al, 2010, p.1430). Part of this research is to understand the level of engagement fluoridation stakeholders, primarily water managers, felt they had in this policy process. The methodological components of this research will be discussed in the next chapter and will include potentially missed stakeholder engagement opportunities and perceptions on the recommendation.

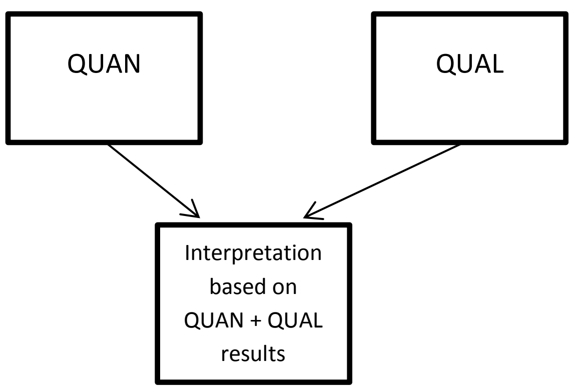
In summary, a policy process theoretical approach can be applied to understanding the policy process of water fluoridation and ways to potentially improve the process and outcomes. The case was made for the application of a synthesized version of Multiple Streams and the Advocacy Coalition Framework to help explain the history of water fluoridation in this country and using several of the concepts of the ACF, namely subsystem actors, it can be understood who the dominant coalitions are and how they have maintained policy power. Some potential concerns related to this policy change were also discussed, including possible oversight of the diverse authorizing environment that includes researchers, agencies, interest groups, the media, policy elites, policy experts within policy subsystems and engaging stakeholders at the state and local level, who in the end must carry out national policy recommendations. Additionally principal-agent relationships were helpful in explaining how this policy, as currently implemented, will need to be carried out and possible challenges associated with a decentralized policy with a centralized policy objective. With possible challenges identified in policy delivery as adopted, other models were considered in the context of the policy process. This has demonstrated the usefulness of policy process frameworks and the enhanced understanding that comes with studying complex policy environments. The next chapter discusses the methodology, analysis, and results of the research and will provide a basis for recommendations and conclusions in the final chapter.

Chapter 5: Methods, Results, and Analysis

The choice of methodology for policy analysis is an important consideration. In order to properly analyze whether a policy decision has been effective, Sabatier's Advocacy Coalition Framework requires a minimum of ten years before the effectiveness of a policy can be determined (Sabatier, 1999). Sabatier (1999) identifies policy literature consensus that a decade or more is the minimum amount of time necessary to complete a policy cycle and get an accurate portrait of the policy's effectiveness. In the case of water fluoridation policy, six or seven decades have passed since the beginning of drinking water fluoridation across the United States. The final policy recommendation in 2015 was a result of careful analysis and scientific study presented throughout governmental reports in the mid 2000's and in other scholarly efforts that had preceded these government efforts. As previously discussed, the 2015 federal recommendation for a flat 0.7 mg/L was made for all drinking water treated with injected fluoride compounds throughout the United States. The analysis that resulted in this recommendation was almost exclusively quantitative and from highly technical scientific reports. The analysis performed in this study is to understand the challenges in implementation of the newest policy recommendation. In all likelihood, it will take another ten years, 2025, to be able to accurately analyze the effectiveness of this policy recommendation in the United States.

The methodology used in this analysis was a mixed methods approach, using a combination of qualitative and quantitative tools. This two pronged approach provides an opportunity to fill important gaps in fluoridation policy research and understand how this federal policy change has impacted levels of fluoridation and local policy implementation. A mixed approach was chosen to continue quantitative work done in previous studies and to address qualitative gaps in the policy-making process that are important to the outcomes of the recommendation. There are strengths and weaknesses to mixed methodology use in policy analysis. As both the quantitative and qualitative components of this research are equally important to the interpretation in chapters four and five, this mixed methodology would be considered a triangulation mixed methodology design according to work done by Creswell et al (2003). The triangulation design is equal parts QUAN and QUAL for interpretation (Figure 5). While the analysis is differentiated by qualitative and quantitative methods, the data obtained by each method is meant to complement each other to analyze the same research question (Creswell et al, 2003).

Figure 5: Triangulation Design (Creswell 2003, 2006)



The strength of the mixed methodology helps cover the weaknesses inherent in choosing one or the other method for this research question alone. The quantitative work had a higher sample size and gives a broader picture of water fluoridation in the United States. At the same time, utilizing the qualitative data gives more detail and depth to the question at hand and provides meaningful feedback in regards to the policy recommendation and potential challenges in meeting that recommendation. Traditional strengths of the triangulation design are its intuitive sense and its efficiency (Creswell, 2003, 2006). Identified challenges in using such a method is in collecting and interpreting both types of data and bringing them together in analysis of the research question.

One method is to recreate the 2005 USDA National Fluoride Database study; specifically, the section on fluoride in municipal tap waters. In 2005, the USDA released a study on fluoride in selected beverages and foods (USDA, 2005) intending on assessing the amount of fluoride ingested through various foods and beverages to better estimate fluoride intake and its effect on human health. This study was a significant piece to building the science on total fluoride exposure. The quantitative analysis for this dissertation uses a one-sample t-test using primary data collected by the researcher and is compared to the 2005 study. The data collected begins in 2013 and ends in 2016 to coincide with the final policy recommendation released in 2015 to determine if any effect can be seen on the national fluoride levels since the policy announcement.

The second method is to engage with the street level bureaucrats who are directly affected by the policy decision and who must implement the new standard fluoride level to meet the national standard. Eliciting feedback from water managers and professionals in the water provision industry is an important consideration as it appears that many of these professionals were left out of the fluoride policy decision making process. When examining the final policy recommendation it appears that the professionals who had a direct hand in making the policy recommendation were largely medical professionals, with little mention of water management or professional associations associated with water management groups. None of these water management professionals, organizations or associations were acknowledged in the process until the Federal Register public notice comments were included in the final announcement. This research fills a gap in the policy process, one that is increasingly acknowledged as important, and that is the inclusion of stakeholder engagement in policy decision-making. It appears that this final policy recommendation decision was made, followed by public comment and its review. It does not appear that stakeholder engagement was utilized in any broad or meaningful sense. While stakeholder engagement should be happening during the policy process and before final policy formation and adoption, it is still valuable to use this tool to better understand policy outcomes. These research methods will shed light on the current landscape of fluoridation policy and potential challenges in meeting the recommendation.

Quantitative: Replication of 2005 USDA Survey

In December 2005, the USDA issued a report entitled the National Fluoride Database of Selected Beverages and Foods, in which municipal drinking water from across the country was analyzed by region. The regions were identified as: All Regions, Mid-West, Northeast, South, and West. This report also included well water, but as artificial water fluoridation is meant primarily for surface waters, municipal water is the data that was compared in this paper. Primary data was collected by the researcher in 2014 and 2016 in order to reproduce these earlier results. The 2014 data was collected from the two most populous municipalities served in each state that had Consumer Confidence Reports for the time period and the 2016 data was collected from the three most populous municipalities served. Generally the 2014 data represents reporting results collected online from the 2013 calendar year and 2016 represents 2015 reporting results. Some cities were served by city-owned water providers while others were served by privately owned large scale water providers such as American Water (Amwater.com, 2017).

In order to replicate this study, CCR/Water Quality reports were researched from all 50 states. The 2014 and the 2016 data sets were compiled by the researcher using CCR's required under the Safe Drinking Water Act amendments of 1996 Registered in the 1998 final rule (Fed Reg Vol 63. No. 160, 1998). CCR's are an important tool to encourage transparency and accountability in drinking water treatment and provision. They are especially important for consumers to understand what compounds exist in the drinking water and at what levels. These reports also reveal whether water providers have received any violations. CCR's identify the amount of fluoride in the water either through natural sources in surface or ground waters or artificially supplemented by the water provider to aid in dental caries prevention. Generally in CCR's the result is a mean result from the course of yearly draws, although in some cases there have been single draw results or median results published. For the usefulness of this type of data analysis all average statistic results would be beneficial to list, a median result is significant as it represents the middle point of results in a distribution, a mean result with identified high and low level detections is beneficial as well as it represents a level one can expect on average, and a mode statistic is helpful as it would list the fluoridation level recorded most frequently. The variability in reporting style by water providers can add some uncertainty in the results collected for this analysis and makes a uniform reporting style helpful. In order to replicate this USDA study, there are potential replication issues and uncertainty in the results. For this reason, an additional 50 municipalities were added to the 2016 data set in order to improve confidence. Since CCR's are required to meet federal regulations and reporting requirements, this data should be suitable and reliable for analysis.

The USDA sampling (USDA, 2005) was performed using 238 data points from municipal water users in all regions (northeast, mid-west, south, west) of the country and statistical inference results were released. Additionally, the data points were also broken down into the various regions with additional statistical inference results. The data of significance for this replication study from the USDA table are: Waters, tap, all regions, municipal, Waters, tap, Mid-West, municipal, Waters, tap, Northeast, municipal, Waters, tap, South, municipal, Waters, tap, West, municipal. The survey results were published in the 2005 report and Table 5 illustrates the results of interest for this study.

Table 5: Municipal Tap Water Data (USDA, 2005)

USDA National Fluoride Database

Item	Mean ppm	Mean mcg/ 100g **	Std Error	Num datapts	Min Value	Max Value	Lower 95% EB	Upper 95% EB
Water, bottled, VOLVIC	0.34	34		1				
Water, bottled, store brand	0.16	16		11				
Water, frozen (ice), fast food type	0.11	11		3				
Waters, tap, all regions, all (includes municipal and well)	0.71	71	2.8	288	1	193	66	77
Waters, tap, all regions, municipal $	0.81	81	2.9	238	2	193	75	86
Waters, tap, all regions, well	0.26	26	4.8	50	1	162	17	36
Waters, tap, Mid-West, all (includes municipal and well)	0.88	88	5.1	68	4	167	78	98
Waters, tap, Mid-West, municipal $	0.99	99	4.6	52	4	167	89	108
Waters, tap, Mid-West, well	0.53	53	12.2	16	5	162	27	79
Waters, tap, Northeast, all (includes municipal and well)	0.69	69	7.5	56	2	193	54	84
Waters, tap, Northeast, municipal $	0.74	74	7.7	52	2	193	58	89
Waters, tap, Northeast, well	0.09	9	3.0	4	4	17	4	17
Waters, tap, South, all (includes municipal and well)	0.76	76	4.6	100	1	191	67	86
Waters, tap, South, municipal $	0.93	93	4.0	80	9	191	85	101
Waters, tap, South, well	0.10	10	1.6	20	1	30	6	13
Waters, tap, West, all (includes municipal and well)	0.47	47	4.8	64	3	135	38	57
Waters, tap, West, municipal $	0.51	51	5.5	54	3	135	40	62
Waters, tap, West, well	0.24	24	4.3	10	5	48	14	34

The data analysis for this study would have been performed when the optimal level of fluoride was the range 0.7-1.2 mg/L and the recommendation was still calculated based on local temperate conditions and water consumption rates. As such, the methodology used in performing this analysis is of some concern in terms of understanding the impact of the new policy regime. With understanding of how fluoride levels were determined at the time, the USDA would have adopted a latitudinal reporting structure instead of a regional structure. The assumption for this study should have followed the general policy assumption of the time that areas in the north would likely have higher fluoride levels due to cooler temperatures and lower water consumption rates, the mid-west area would have lower fluoride levels than the North but higher than the South, and the southern-most areas would be the lowest in fluoride levels due to higher water consumption rates due to higher yearly temperatures (PHS Recommendation, 2015). The regional structure of the USDA 2005 report is concerning since the West region would include states as far north as Washington and as far South as California, which has large variation in its yearly temperatures and ignores water fluoride level calculations at the local level that would have been present at the time. This regional reporting style goes against the intention of the policy at the time.

The method in which this study was replicated could lend itself to regional statistical inference but since the nation is supposed to move to a uniform 0.7 mg/L water fluoridation level, regional reporting may be less important. At the time of this 2005 report, the policy was 0.7-1.2 mg/L across the country for optimal fluoridation. Table 5 illustrates that the West came in well under the 0.7 minimum threshold with a mean of 0.51 mg/L and with a 95% CI of 0.4-0.62 mg/L. Further, the Northeast had a lower mean (0.74 mg/L) than the Mid-West (0.99 mg/L) and the South (0.93 mg/L), which is not how the policy was intended with the North supposed to have higher levels than the South. Some of this result could be due to regionalization variation in reporting. One of the most critical components of this study are the statistical inference data results for all municipal regions. The results reveal a mean for all regions is 0.81 mg/L with a 95% CI of 0.75-0.86 mg/L with 238 observations and a minimum value of 0.02-1.93 mg/L.

The results of the replication of the study collected by the researcher are broken down into three results, 2014 data (100 observations, Table 6), 2016 data (150 observations, Table 7), and a combined data set of 2014 and 2016 observations (250 observations, Table 8). Inferential statistical results in conjunction with mean testing will provide quantitative analysis of water fluoridation implementation over the past five years. A one-sample mean t-test was utilized to hypothesize a mean based on the recommendation. The hypothesized mean is 0.7 mg/L as recommended by the Federal Panel on Community Water Fluoridation. Utilizing this test allows for detection of a statistical difference between the sample mean and the hypothesized population mean. The results are below.

1. Year 2014 Data:

Ho: $\mu = 0.7$ mg/L versus Ha: $\mu \neq 0.7$ mg/L

Ho: $\mu = 0.7$ mg/L versus Ha: $\mu > 0.7$ mg/L

Ho: $\mu = 0.7$ mg/L versus Ha: $\mu < 0.7$ mg/L

Table 6. Results of 2014 Data

Results of 2014 Data	
Summary Statistics	
Mean ppm	0.692302
Mean mcg/100g	69.2302
Std Error Mean	0.02910797
Num datapts	100
Min Value	0
Max Value	1.3
Lower CI	0.634545
Upper CI	0.750059
1-Alpha	0.95
Test Mean T-Test	
Test Statistic	-0.2645
Prob > [t]	0.792
Prob>t	0.604
Prob<t	0.396
Significance: * 10% level, ** 5% level	

The 2014 data set (Table 6) is characterized by the following inferential results using the statistical software JMP: the mean is 0.692302 mg/L across the country with a 95% CI of 0.6345455-0.7500585 mg/L which captures the 0.7 mg/L recommendation. This data included one hundred observations ranging from 0.0 mg/L (major municipalities that do not fluoridate) to 1.3 mg/L. Additionally, several t-tests were performed using JMP with a hypothesized value of 0.7 mg/L. The first test results in failing to reject the null hypothesis and not accepting the alternative hypothesis. Similar results occur for the other t-tests with Ha: $\mu > 0.7$ mg/L and Ha: $\mu < 0.7$ mg/L in which the results fail to reject the null hypothesis. These results reveal the policy recommendation could have been met during this timeframe but as can be seen, the variation in observations from large municipal areas serving thousands to millions of Americans ranged from 0 to 1.3 mg/l which is almost twice the recommended fluoride level in the upper range.

2. Year 2016 Data:

Ho: $\mu = 0.7$ mg/L versus Ha: $\mu \neq 0.7$ mg/L

Ho: $\mu = 0.7$ mg/L versus Ha: $\mu > 0.7$ mg/L

Ho: $\mu = 0.7$ mg/L versus Ha: $\mu < 0.7$ mg/L

Table 7. Results of 2016 Data

Results of 2016 Data	
Summary Statistics	
Mean ppm	0.652115
Mean mcg/100g	65.2115
Std Error Mean	0.0239335
Num datapts	150
Min Value	0
Max Value	1.855
Lower CI	0.604822
Upper CI	0.699408
1-Alpha	0.95
Test Mean T-Test	
Test Statistic	-2.0007
Prob > [t]	0.0472**
Prob>t	0.9764
Prob<t	0.0236**
Significance: * 10% level, ** 5% level	

The 2016 data set (Table 7) has the following inferential characteristics: the mean is 0.652115 mg/L across the country with a 95% CI of 0.604822-0.699408 mg/L, failing to capture the 0.7 mg/L final recommendation. This 2016 data includes one hundred fifty observations ranging from 0.0 mg/L (major municipalities that do not fluoridate) to 1.855 mg/L. Additionally, several t-tests were performed using JMP with a hypothesized value of 0.7 mg/L. The first test results in rejection of the null hypothesis and accepting the alternative hypothesis. The result is significant at the 5% level. This result signifies with a 95% probability that the national average is not equal to 0.7 mg/L. Furthermore the t-tests Ha: $\mu > 0.7$ mg/L fails to reject the null hypothesis and Ha: $\mu < 0.7$ mg/L rejects the null hypothesis and accepts the alternative hypothesis which is significant at the 5% level. The results indicate the national mean is not equal to the 0.7 mg/L policy goal, but is likely less than the policy goal. Results confirm that the policy recommendation is likely not being met over the 2014-2016 timeframe. However, what is reflected in the data is the reduction in variability from 0.11 mg/L in the CI from 2005 and 2014 to 0.09 mg/L in the 2016 data set. This could reflect a positive trend, where the new national policy is working to narrow the variation in fluoride delivery. Additionally, the data shows in this replicated model that the overall mean has dropped from 0.81 mg/L in 2005 to 0.69 mg/L in 2014 and 0.65 mg/L in 2016. This trend could indicate reduced exposure to fluoride from drinking waters on average nationally, a goal of the policy final recommendation. While the final policy goal may or may not truly be met, the data indicates that one of the desired outcomes of the policy recommendation is being met with a reduction of exposure through drinking water, likely reducing total exposure for most people who drink municipal tap water (PHS recommendation, 2015).

3. Year 2014-2016 Combined Data:

Ho: $\mu = 0.7$ mg/L versus Ha: $\mu \neq 0.7$ mg/L

Ho: $\mu = 0.7$ mg/L versus Ha: $\mu > 0.7$ mg/L

Ho: $\mu = 0.7$ mg/L versus Ha: $\mu < 0.7$ mg/L

Table 8. Results of Combined Data Sets

Results of Combined Data Sets	
Summary Statistics	
Mean ppm	0.6681898
Mean mcg/100g	66.81898
Std Error Mean	0.0184923
Num datapts	250
Min Value	0
Max Value	1.855
Lower CI	0.631769
Upper CI	0.704611
1-Alpha	0.95
Test Mean T-Test	
Test Statistic	-1.7202
Prob > [t]	0.0866*
Prob>t	0.9567
Prob<t	0.0433**
Significance: * 10% level, ** 5% level	

The final table (Table 8) represents the 2014 and 2016 combined data sets. This potentially provides wider insight into what the policy outcomes are since the federal recommendation was made. The combined model reveals a mean of 0.66819 mg/L across the country with a 95% CI of 0.6317685-0.7046111 mg/L, capturing the 0.7 mg/L recommendation. The combined model has 250 observations, ranging from 0.0 mg/L (major municipalities that do not fluoridate) to 1.855 mg/L. Additionally, several t-tests were performed with a hypothesized value of 0.7 mg/L. The first test results in failing to reject the null hypothesis and not accepting the alternative hypothesis. This confirms the true mean could possibly be 0.7 mg/L. While not significant at the 95% level, this result is significant at the 90% level. A similar result occurs for the second t-test with Ha: $\mu > 0.7$ mg/L indicating the mean is not greater than 0.7 mg/L.

However, the final t-test with Ha: $\mu < 0.7$ mg/L results in rejecting the null hypothesis and accepting the alternative hypothesis. This result is significant at the 5% level and indicates that the data is strong enough to argue the mean is less than 0.7 mg/L but not significant enough to say it is not equal to 0.7 mg/L.

Another way to interpret the data is to examine the mean and the variability over that time period compared against the 2005 data. The mean is far lower than the 2005 data, from 0.81 mg/L to 0.66 mg/L and the variability was reduced from 0.11 mg/L variability in the true mean to 0.07 mg/L variability in the true mean with the top end of the 95% CI capturing the policy target. This could indicate that the policy recommendation had an impact before the final recommendation was announced in 2015. In conclusion, these results indicate that the policy recommendation is likely to have been met during the 2010-2016 timeframe. How closely it has been met across the nation is important for future researchers to explore. One question that remains is whether setting the fluoride injectors at 0.7 mg/L equals draws of 0.7 mg/L for use in reporting or CCR reports. It could be considered open to interpretation whether one moment in time (CCR draw) means the policy cannot meet the recommendation if it is not 0.7 mg/L every time or if setting the fluoride level to 0.7 mg/L is enough to meet the goal.

Qualitative: Water Manager Stakeholder Engagement Survey

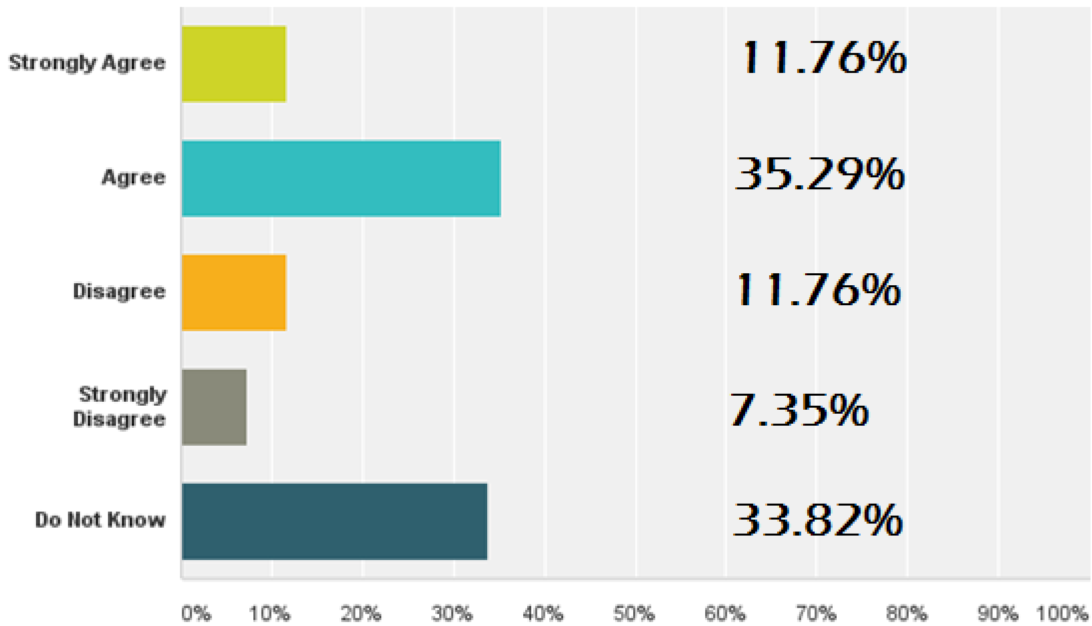
One of the most likely places to engage water stakeholders is through the American Water Works Association (AWWA). The AWWA is a professional organization for those who treat and manage water. While the AWWA does engage with its members at conferences regarding the handling of fluoridation and its perceptions in the community, there was no evidence to show that the AWWA, any of its state-affiliated chapters, or members had been consulted about the plausibility and challenges facing local water districts in meeting the new policy recommendation (PHS recommendation, 2015). This methodology attempts to understand this oversight using a qualitative survey to understand stakeholder perceptions of water fluoridation practices in the United States. The survey was distributed over the late spring and summer of 2016. In order to protect the identity of those taking the survey, it was distributed by individuals other than the principal researcher but its reach was across the entire country.

Following in the tradition of qualitative research methods, this survey follows a structured style of engagement, in which all stakeholders receive the same series of questions with a pre-determined number of response categories. The questions were standardized, ordered, and phrased the same for all respondents. Survey methodology is arguably the best method in collecting original data for describing a population too large to observe directly (Babbie, 2001). There are over 18,000 community water systems providing fluoridated water in the United States (CDC, 2014). Add another 25% to that number that are CWS's that do not fluoridate and that might begin to number the true population of water managers that have water fluoridation oversight (approximately 22,500) (CDC, 2014). The number of respondents was 68 out of hundreds sent out, and they did not receive any compensation or any other incentives for participation in any way. With the large number of water systems and managers in this country, 68 responses are not generalizable to the true population. The sampling for this study was purposive, in that there was a specific group in a particular field used for the survey (Babbie, 2001). The positives of purposive sampling for this research are that experts in the field respond, but the negatives could include researcher bias and generalization to the true population. As this survey is geared toward engaging those who are at the frontlines of the policy environment and implementing the recommendation, it can be understood that the responses should be contextualized as such, but should not be considered bias by the researcher.

Prior to taking the survey there was an information page describing the research study (Appendix D). The information page included information on the policy recommendation and that the purpose of the survey was to understand the impact of the policy recommendation at the local level. Additionally, other institutional research IRB-related specifications were included. Some of the IRB compliance components ensured confidentiality of the research collected, that respondents could choose not to participate and could stop at any time, and that there was no understood benefit to the respondent. Continuing to the survey, respondents agreed that they had read the information, voluntarily agreed to participate, and were at least 18 years of age.

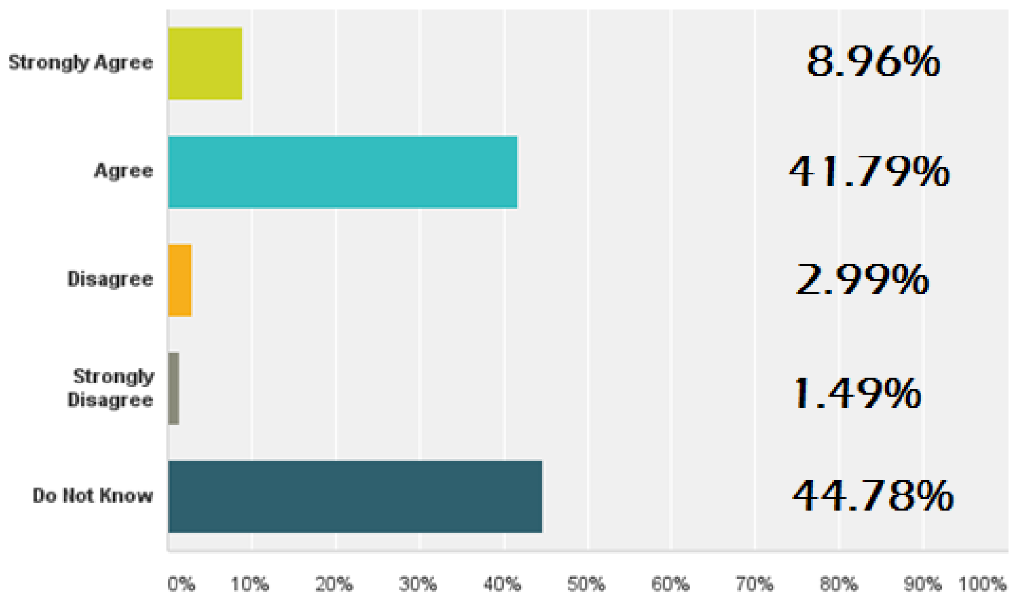
There was an introductory demographic question (Appendix D) in order for the respondent to self-identify as either representing a rural or urban water system. Interestingly enough there was an even split between those identifying as urban and those identifying as rural: urban = 34 and rural = 34 which makes generalizability more difficult as the vast majority of Americans live in urbanized areas/urban clusters (U.S. Census Bureau, 2010). This question was intended to help contextualize the responses for the following questions but did lend itself to user knowledge of urbanized areas/urban clusters versus rural areas. Potential disparity in policy outcomes in water fluoridation could exist depending on whether the policy is implemented in urban or rural areas. The cost-benefit component of community water fluoridation is significant for larger water systems; however, as the population served by the CWS is reduced the cost-benefit drops significantly (PHS recommendation, 2015). In communities of 20,000 or more people, the cost is around $0.50 per person compared to a $35.90 benefit (PHS recommendation, 2015). For communities of 5,000 or less people the cost is around $3.70 per person with benefits around $28.70 annually (PHS recommendation, 2015). The cost-benefit component is still a significant driver in this policy area in both demographics, but there is still an identified cost-benefit difference in urban delivery versus rural delivery. This is not to suggest that this could be a barricade in policy implementation, however, the possibility should not be ruled out. The result of this demographic question were split, with 34 responses for each, urban and rural. The results with an equal mix of urban and rural respondents will give a middle ground perspective on the policy recommendation and its implementation at the local level but again limits generalizability to the larger water manager population.

Figure 6. Question 2: As a stakeholder in Community Water Fluoridation programs, water manager's input was considered in adopting the new fluoridated water recommendation.



The next question is the beginning of the stakeholder engagement survey, with questions relating to the policy recommendation and the feasibility of implementation at the local level. The question is meant to elicit feedback regarding whether water manager's feel as though they were represented in the process to recommend a new water fluoridation level for the country. The result of this question is mixed (Figure 6). Almost fifty percent of respondents indicated that water manager's input was taken into consideration in developing the final policy recommendation, while more than half of the respondents disagreed, strongly disagreed, or did not know if water manager's input was taken into consideration. Do not know reflects the degree of uncertainty around this policy issue and leaves this question in somewhat murky waters but does exemplify that engagement, if there was an effort made, was not engaged in by the majority of stakeholders in the water management profession.

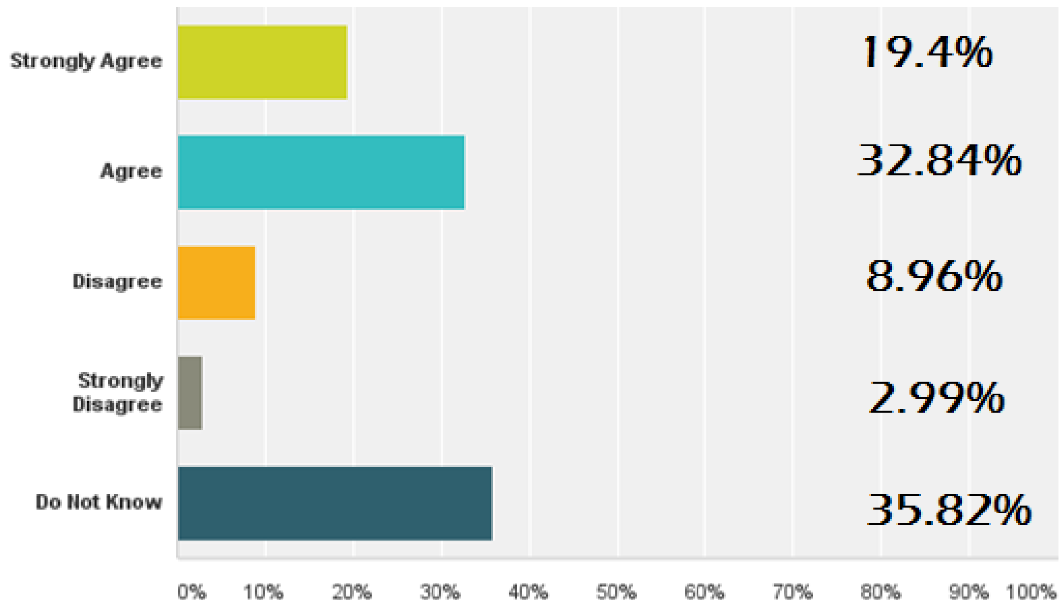
Figure 7. Question 3: The American Water Works Association (AWWA) had input into adopting the 0.7 mg/L fluoridated water level.



To get a better picture of how engaged the AWWA was in this recommendation, the next question examined whether the water management professional association is thought to have had input or had a seat at the table in regards to the adoption of the new policy recommendation. The responses to question three are primarily one of two responses, agree and do not know; which comprises over 85% of the responses for this question (Figure 7). Do not know received the most responses (44.79%), which could possibly allude to the gap in the policy process. This bi-modal nature of these responses is interesting, as almost half agree or strongly agree that the AWWA had input into the policy adopted goal of 0.7 mg/L, while almost half did not know if the AWWA had input into the policy recommendation. These results indicate that some of the water professionals, the street level bureaucrats in this case, were engaged in the decision-making process but what the scope of this engagement was in uncertain.

As policy decision-making grows beyond the Iron Triangle, it can include Issue Networks (Heclo, 1978) to which water fluoridation policy and policy-making could be considered. Contemporary policy making has been forced to include stakeholders as a part of the process of decision-making (Wamsley et al, 1990, Bingham et al, 2005). Stakeholder engagement efforts are argued to improve policy outcomes and to enhance participation across the layers of America's federalist environment (Wamsley et al, 1990, Bingham et al, 2005). Question four is meant to incorporate this more contemporary policy decision-making framework into the context of water fluoridation policy.

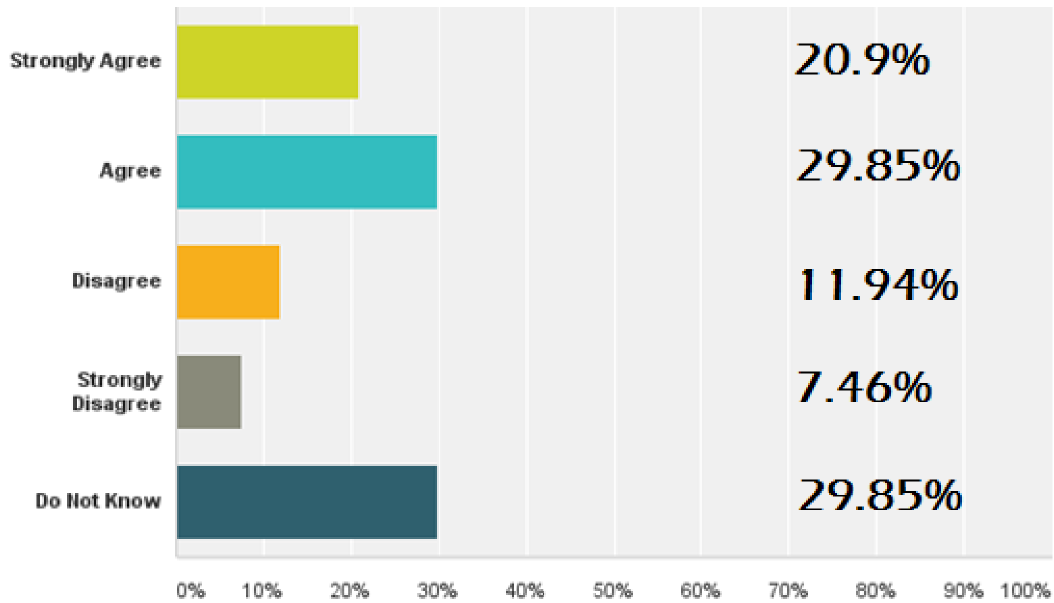
Figure 8. Question 4: National fluoridation policy experts involved a broad range of stakeholders in the process of adopting the new optimal water fluoridation level for the United States.



Question four reveals a similar pattern as previous responses, in that many of the respondents agreed that a broad range of stakeholders had been engaged regarding the new policy recommendation or they did not know. The highest response again revealed that most respondents do not know if a broad range of stakeholders were engaged in this process (Figure 8). Based on a scan of the policy recommendation panel, it could be argued that a broad range of health professional stakeholders had been engaged, but no panelists who delivered the recommendation were Professional Engineers (PE) for water utilities or related organizations. Given that these professionals are the ones that will actually implement the policy, this is an important stakeholder group that may not have been broadly considered. Further, if professional engineers had a seat at the table, then it was not reflected in the federal announcement, which was an extensive list of experts.

Specifically, the U.S. DHHS Federal panel on Community Water Fluoridation consisted of approximately 11 Masters of Public Health experts M(S)PH's, 5 Medical Doctors (MD's), 11 Doctor of Philosophies (PhD's), and 10 Doctors of Dental Medicine/Surgery (DDS/DMD's). "Panelists included representatives from the CDC, the National Institutes of Health, the U.S. Food and Drug Administration, the Agency for Healthcare Research and Quality, the Office of the Assistant Secretary for Health, EPA, and the U.S. Department of Agriculture." (Public Health Reports, 2015) This is an impressive collection of some of the top researchers in medical, dental, and research fields regarding water fluoridation, but it does not appear that engineering and water utility professionals were included in this group. Equally as important, if this is the case it would not appear that the feasibility of the complex nature of meeting a specific chemical target in drinking water was evaluated to its fullest extent. The panel did perform an overview of public comments, which included feedback from "water supply professionals." This which could be considered a weak form of stakeholder involvement akin to an informational session, but this was after the policy recommendation had been made and was opened for public comment. It can be argued that because the recommendation had been made, many stakeholders may not have believed their professional opinions in a public comment forum would add value to the decision, which was effectively already made. (Public Health Reports, 2015)

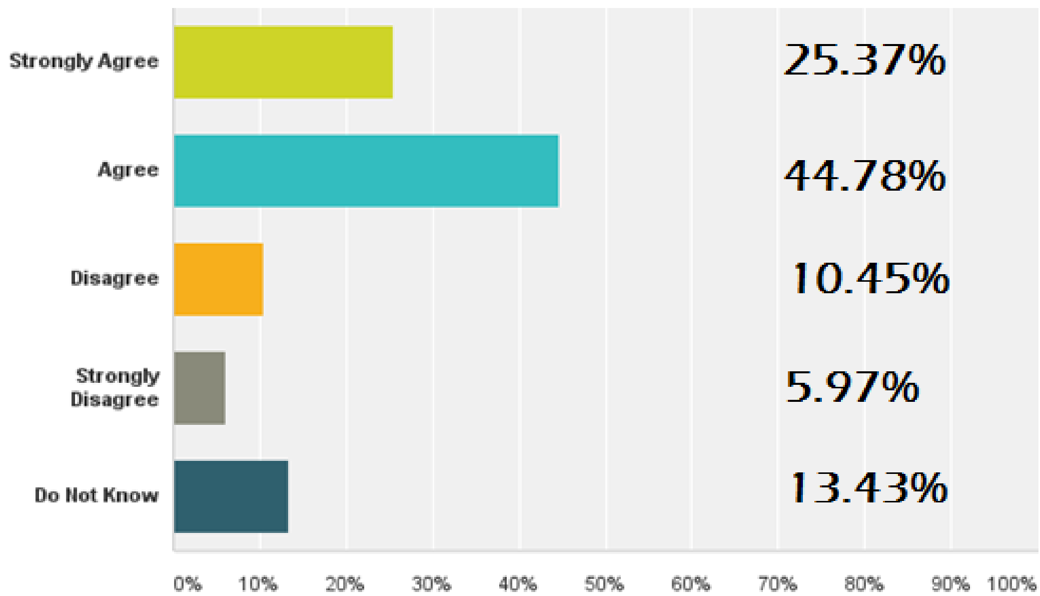
Figure 9. Question 5: National fluoridation policy experts understand the complexities of delivering the new 0.7 mg/L fluoridation level to local communities.



Even if broad stakeholder engagement did not occur, this does not necessarily mean that the policy recommendation was inaccurate or that the professionals who made it did not have the expertise to make this recommendation. Mass water fluoridation is a complex process that requires the efforts of local engineers and related professionals at water utilities across the country. This can be seen in part as local water fluoridation across the United States is highly variable in terms of the level of fluoridation needed in each community. Question five is meant to help to understand the first-hand knowledge and experience of those who treat water versus those who make recommendations without that direct experience. The good news is that over half of respondents agree or strongly agree that the complexities involved in meeting the recommendation are understood by the policy experts, i.e. the panel on community water fluoridation (Figure 9). The other half of respondents disagreed, strongly disagreed, or did not know whether policy elites understood the complexities involved in water provision and hitting a specific water quality target. Interestingly, agree and do not know received the most responses to this question. This could be indicative of the experience different water professionals had during this policy process.

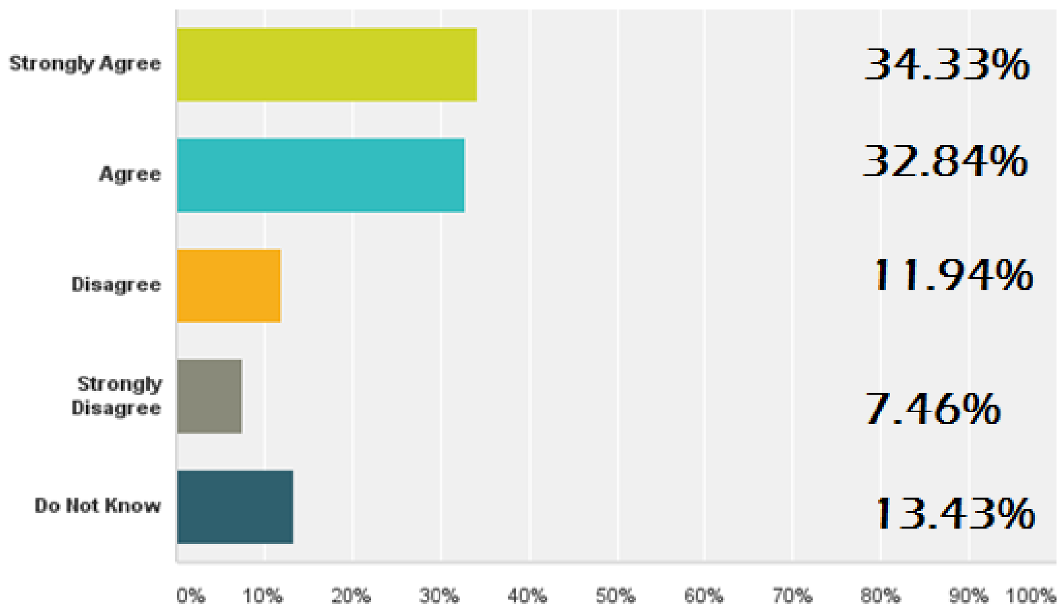
One of the key questions for any policy transition is what resources are available and what issues may arise to ensure the successful implementation of this new policy. The CDC in 2015, "is reviewing available data and collaborating with organizations (AWWA) of water supply professionals to update operational guidance" (Public Health Reports, 2015, p.10). Additionally, the CDC is "supporting local and state infrastructure needed to implement and monitor the recommendation. Examples of this support include maintenance of the Water Fluoridation Reporting System; and provision of training opportunities for water supply professionals" (Public Health Reports, 2015, p.10). While this is evidence of some federal support for the implementation of this recommendation, stakeholder framework and implementation research would suggest that decision-making without input from the water supply profession during the process of the policy recommendation could potentially harm outcomes in this policy area. Without a federal mandate and with State regulation lagging in enforcement, it is likely that water fluoridation will decidedly remain a local issue with inherent variability across the nation.

Figure 10. Question 6: Community Water Fluoridation programs can consistently deliver the newly recommended fluoridated water level of 0.7 mg/L across the United States.



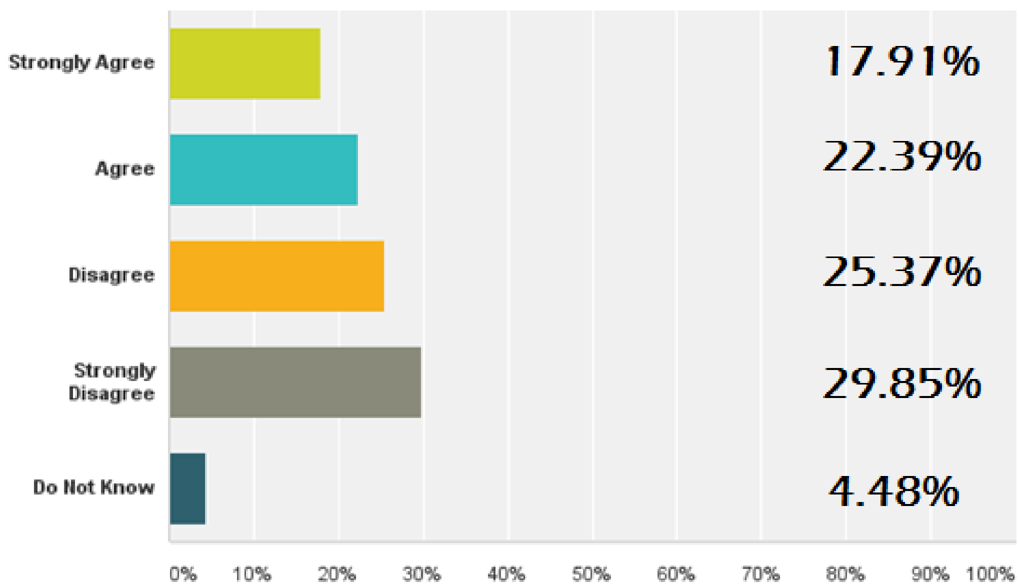
Question six is meant to understand if those who deliver water to the consumer base across the country believe that the recommendation can be consistently met at such a fixed level. Water quality treatment, including water fluoridation, is a complex process and confirming that this standard can be met day in and day out is of critical importance to successful implementation. Almost seventy percent of respondents agreed or strongly agreed that this target could be met with the existing infrastructure and local delivery mechanisms of water fluoridation policy in this country with agree receiving the most responses (Figure 10). When compared against the data collected for the USDA replicated study, this result is contradicting. The USDA study found it was rare to find a mean or median level across water utilities that hit this specific mark. It will remain to be seen if Community Water Systems (CWS) can indeed hit the 0.7 mg/L mark in coming years.

Figure 11. Question 7: Our community fluoridates water at 0.7 mg/L.



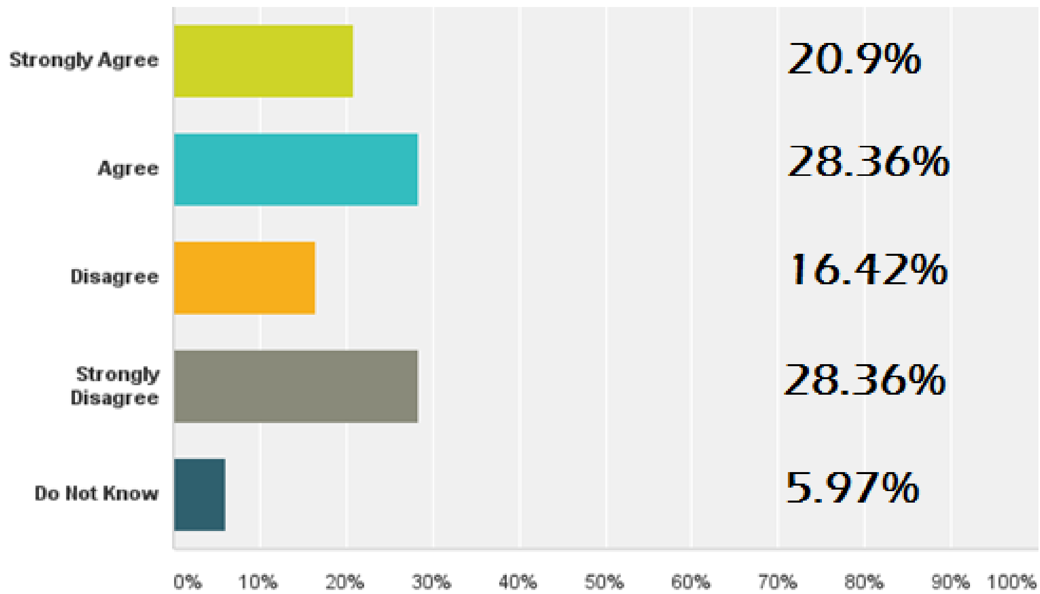
Some water systems may already be meeting this standard and question six is a direct question regarding the water fluoridation level in the respondent's community and whether it meets the policy recommendation. As this question was distributed in 2016, communities have had a year to make the proper changes since the final recommendation was announced and three years since the policy was initially announced. Of the 67 respondents, roughly 67% agreed or strongly agreed that their community currently fluoridates their water at the 0.7 mg/L level (Figure 11). Roughly one third of respondents answered that their community does not fluoridate at the policy recommended level or they do not know if their community fluoridates at the 0.7 mg/L level. It is surprising that 13% of these professionals do not know if their community fluoridates at the 0.7 mg/L but this could have something to do with their experience or professional responsibilities. It is possible that these individuals were not directly responsible for that particular aspect of water provision, but it would be hard to understand an engineer at a local water system would not know or would not be able to find out if their community compliant with the standard. This highlights one of the ongoing challenges with surveys and how to interpret survey responses.

Figure 12. Question 8: The federal government should make fluoride policy and decide fluoride limits for local water systems.



Another ongoing issue with water fluoridation policy, are questions around who should mandate these fluoride policy levels? Should this come directly from the federal government or should there be guidance and advisement from the federal government? Given this, question eight reflects this issue of perceptions related to how federal regulation and decision-making is interpreted at the local level by those tasked with meeting regulations from national policy decision-makers. This was the first response that disagree and strongly disagree had more responses than agree and strongly agree, with strongly disagree the highest response rate (Figure 12). In a policy area that is implemented at the local level and in some cases regulated at the state level this result is not a surprising one. The response data should also not be surprising given that public engineers, who themselves must undergo rigorous education and testing criteria, may perceive that they should be critical stakeholders in this decision at the community water level. An important area of consideration however, is that this question could yield different responses depending upon the political, socioeconomic and geographic orientation of the respondent. This may be an important area for future research as these local decisions impact public health and infrastructure. Although, the fact that this policy recommendation is not enforceable by any federal agency lends itself to continued local interpretation and implementation; largely according to local perceptions of water fluoridation policy.

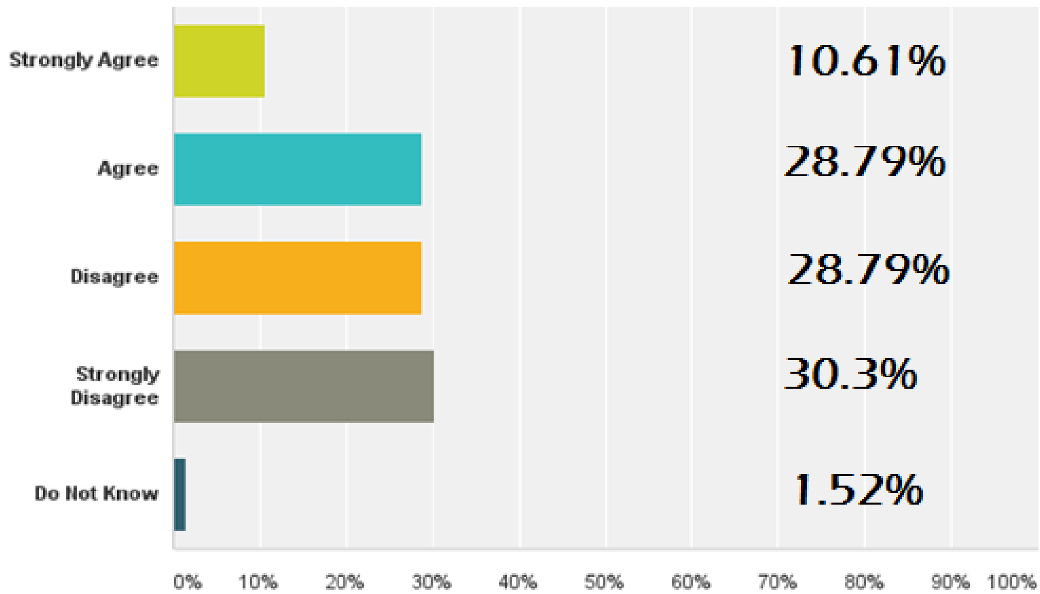
Figure 13. Question 9: State governments should make fluoride policy and decide fluoride limits for local water systems.



The next question attempts to understand whether local policymakers believe that policy should be made closer to its source of implementation at the state level. This question focused on bringing the regulation and decision-making down a level to where the current policy environment resides. Looking back on some of the multitude of cases and the subsequent denial of certiorari by the Supreme Court and (Balog, 1997) deferred this issue to the states, arguing that the states are tasked with maintaining supervision over this policy area. As already discussed, this organization can be challenging with the recommendation coming from federal agencies and a federal agency panel, and some states wielding more control over their policy and implementation destiny than others. The results from question nine are almost evenly split (Figure 13). Interestingly, agree and strongly disagree had the same response results so some respondents felt the state should be tasked with the policy decision-making and others were strongly opposed. In a policy area that is decidedly state-based, as evidenced by earlier Supreme Court decisions, and since local entities are creatures of the states, these response rates are interesting as this is where water fluoridation policy remains.

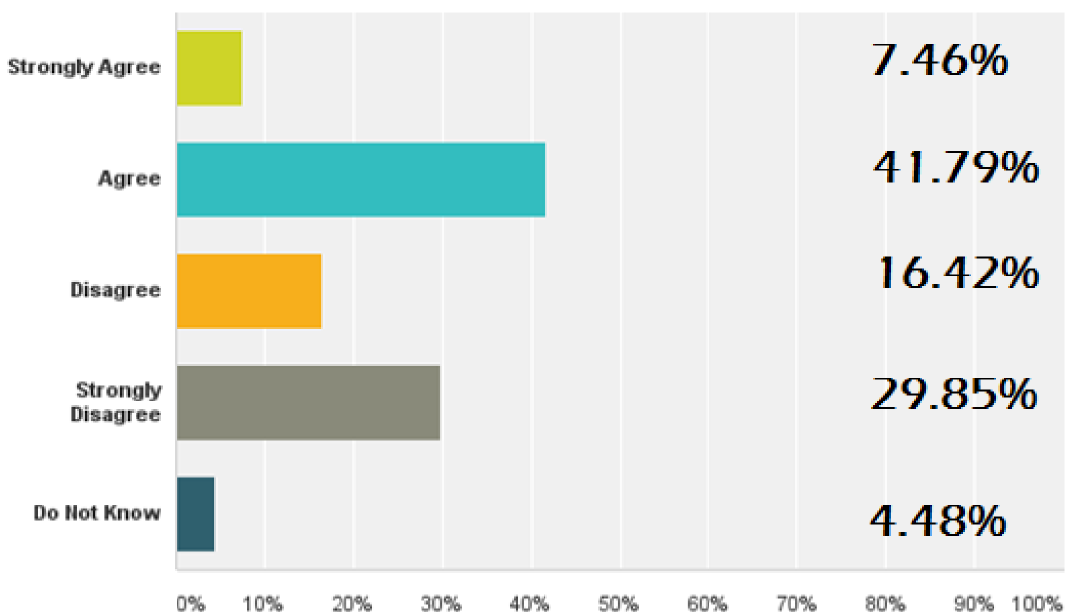
While there is federal oversight over bottled water with fluoride additives and in other fluoride supplements over the counter, states are ultimately tasked with community water supply fluoridation oversight. Some states do a better job than others, as demonstrated in chapter one with the variability in state regulations and local ordinances in place around the country. The responses to this question of States making fluoridation policy, as compared to the same question asked in the context of federal or local regulations in this survey, provides the highest tally of strongly agree or agree responses showing the strongest support for state control in this policy area. In conclusion, water fluoridation policy is state owned but the variability in state involvement lends itself to increasing variability at the local level.

Figure 14. Question 10: Local water managers should be able to continue to fluoridate water at the level they deem appropriate based on local conditions.



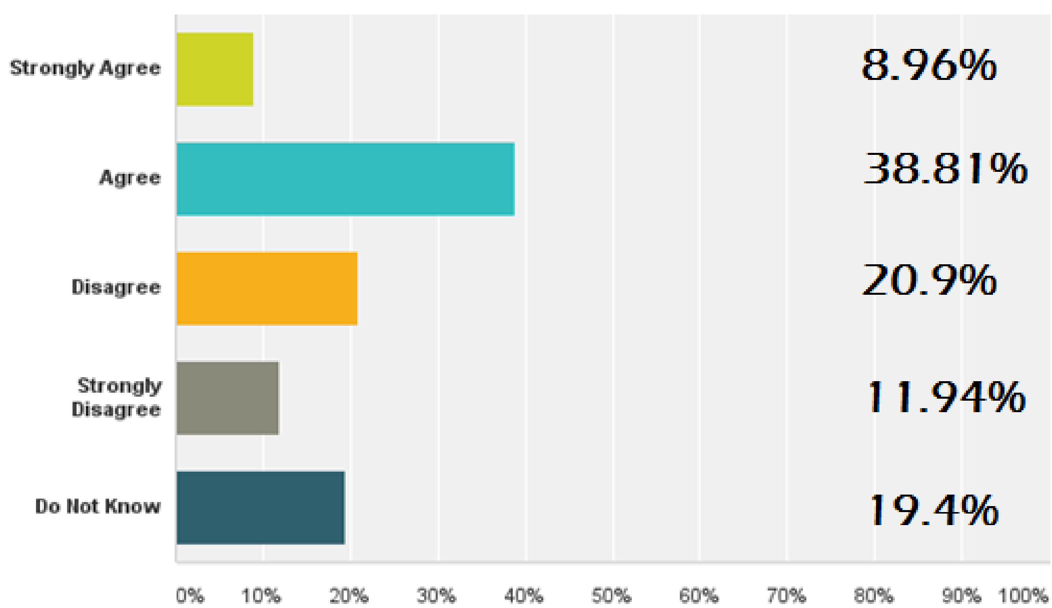
As mentioned earlier, there is ongoing discussion about the level where policy decision should be made and implemented. Question ten underscores the beginning of this policy lifecycle and localities could determine their own fluoride level based on climate and water intake within a 0.7 to 1.2 mg/L range. The results for question 10 indicate that the majority of respondents are steering away from the local decision-making aspect of the policy and moving toward favoring a policy recommendation from the state, but less so for a federal policy recommendation. In many ways, this can be considered the status quo, since the states have been tasked with this policy from the beginning of these policies creation across the states. Almost sixty percent of respondents disagree or strongly disagree that local water managers should decide what level to fluoridate the water supply (Figure 14). On the other hand, nearly forty percent strongly agreed/agreed with the idea that there should be complete local control over this decision. The results from this series of questions are mixed, with approximately the same number of responses wishing to have the power of decision-making at the local or federal level with a stronger response for the state controlling the policy setting in this area. Consistency and variability with any policy, but especially one that has public health implications, raises ongoing questions about state and local control of water fluoridation and the potential variance that could occur across the states.

Figure 15. Question 11: Other methods of fluoridation should be explored by the federal government to achieve the same public health outcome (using fluoridated salt, milk, supplements which already exist, etc).



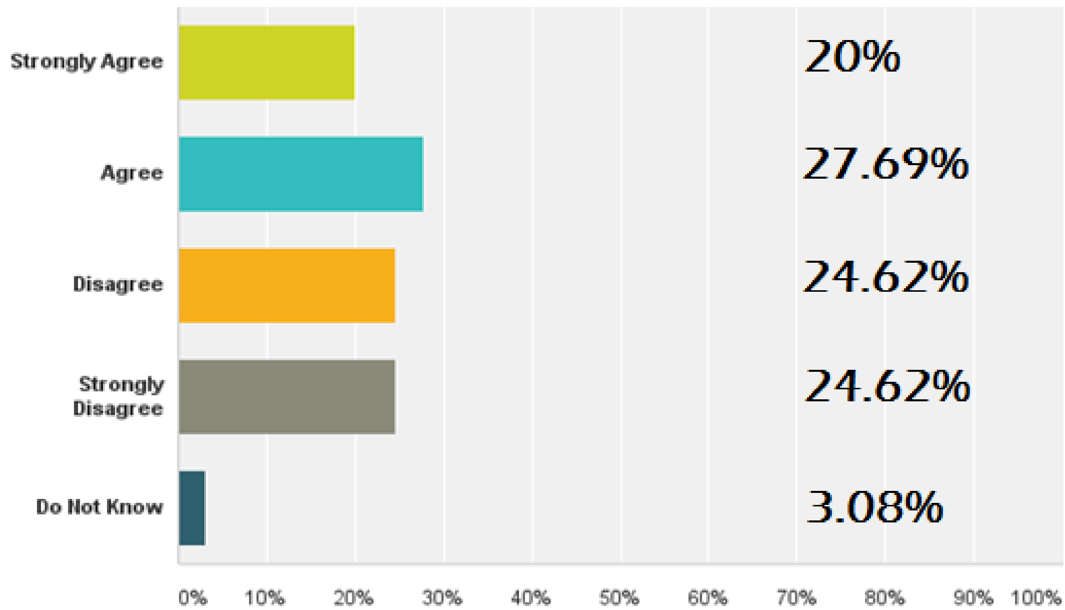
With ongoing discussion about the levels of fluoride and how these policies are developed, there may be other policy choices that scientific research supports. There have been studies across the world on the effectiveness of alternative methods of fluoridation that are used successfully in other countries and even some studies in the United States (WHO, 2009, WHO, 2005). More in depth discussion of this particular topic is included in the final chapter but some of these studies have focused on; milk fluoridation, salt fluoridation, ramping up fluoride supplements or adding to vitamins to tap water (WHO, 2009, WHO, 2005). It is, however, useful to understand if additional research and/or implementation efforts provide evidence of alternative best practices with fluoride treatment. The results of this question of whether alternative models should be explored received surprisingly supportive feedback with almost half of the respondents strongly agree/agreeing with this idea. However, almost half of the respondents disagreed/strongly disagreed. The agree response generated the most singular responses (41.79%), which sends a message that exploring other models may be an important consideration for state and local policymakers moving forward (Figure 15).

Figure 16. Question 12: Community Water Fluoridation programs, as they are currently implemented in this country, are equitable.



One of the primary objectives of water fluoridation policy is to provide equitable access to the benefits of fluoride to all Americans. Before the new policy recommendation, some areas of the country chose not to fluoridate, others fluoridate according to the recommended standard, while others fluoridate at the level deemed appropriate in their region. Similarly, enforcement and compliance in some states is mandatory and in others it is not enforced by the state but left to locales to decide and comply. Urban and metropolitan water systems are most likely to be able to meet the infrastructure requirements and have the technology and engineering capacity to meet the goal versus more rural systems which may have aging infrastructure and less professional and technical capacity. As such, this question focuses on the potential variability across the country in implementation, enforcement, and infrastructure. Approximately forty percent of respondents agree with the idea that water fluoridation policy is an equitable policy across the United States (Figure 16). It could be argued that the opportunity for water systems to choose whether or not to fluoridate and whether those in the community have a voice in that decision is an important consideration of equity. Several large cities in the United States choose not to artificially fluoridate their surface waters to meet the recommendation, and that is their right within this policy area. Equity should not be used synonymously with equality, as in the case of water fluoridation practice not all communities are equal. Equitability leaves this policy with enough flexibility in the fairness of community decision-making to allow for the differences in implementation across states. Ensuring equity is an admirable goal but is also one that is defined and interpreted differently among individuals and organizations. Further, the nature of this policy environment, where authority is left to the states but the policy is set by the federal government and implementation is left to the local level, leaves some ambiguity and variability in policy implementation and potentially policy outcomes.

Figure 17. Question 13: Water consumers should be allowed to opt out of community water fluoridation programs.



The final question focuses on providing choice to the local water consumer (Figure 17). This question also prompts discussion of policy design and implementation options which are more present in contemporary public policy. The question does not relate to communities opting out, as this was built into the original policy recommendation in 1962 (PHS recommendation, 2015). Similar to immunizations, this question relates to opting out for reasons self-identified by individual persons in the community. This is a trend for more contemporary policies to allow for opt out clauses with penalties attached but it does give the individual a choice in compliance. It is true that penalties can be designed as disincentives that severely curtail this policy choice (ACA, Title 1 Subtitle F, 2009-2010). The discussion of affordability, who pays for opting out, and plausibility within the confines of water fluoridation will be discussed along with alternative models in the following chapter.

This question illustrates an almost equal split between agree/strongly agree or disagree/strongly disagree (Table H). Slightly more respondents disagree or strongly disagree that individuals should be able to opt out of community water fluoridation programs. Similar to earlier responses, there is a mixed perspective among water managers but the broader scope of the question is in the design of the policy and in the reality of its implementation across the country.

In conclusion, the double pronged approach of this methodology has added two pieces of key implementation components to water fluoridation policy post-recommendation change. The first method shed some light on current practice at the local level from the time of the recommendation announcement and final recommendation. The second method engaged stakeholders at the local level charged with implementing the recommendation. Both the qualitative and quantitative methodologies combined have added contemporary data following the final policy recommendation in the United States.

The quantitative study, mirroring the 2005 data released in the USDA study of fluoride in select foods and beverages, revealed several key findings. First, the mean water fluoridation level across the country has fallen since the recommendation was made and finalized. Additionally, the variability across the United States was narrowed from 0.11 mg/L in the 2005 set to 0.07 mg/L in the combined set. This is a particularly important number which can be used to point to the response from the CWS at the local level to the policy change. While this data is encouraging toward reducing fluoride over exposure through fluoridated water as it relates to dental fluorosis, the data shows that there is still high variability of policy adoption and implementation which can impact policy outcomes around the United States. The benefit of this policy is thus not realized in some communities and demographic groups.

The qualitative results also reveal understandings of the policy at the local level. The results indicate that water managers and their professional association felt engaged in the policy process despite some evidence to the contrary in the recommendation itself. Also, policy experts understand the complexities involved in delivering this recommendation at the local level. For the most part, communities feel they can meet the policy goal and have been doing so since the final recommendation. As far as what body determines water fluoridation policy, a slight edge is given to the status quo, with state-based policy recommendations and enforcement being the federalist layer of choice. Responses to exploring other models of delivery, equitability, and consumers having the option to opt-out met with mixed results, but enough of a response in each question to be possibly considered by policy-makers moving forward should it reach the agenda once more. There are exceptions in each of these questions which, again, highlight challenges in implementation and policy outcomes. Reinforcing generalizability problems from a limited set of respondents again needs to be reiterated. While this qualitative survey does not meet requirements to suggest these results are representative of the total population of water managers, it can provide insight into particular issues that could possibly use further exploration in the future. The AWWA or the Federal Panel on Community Water Fluoridation, if it were to ever put water fluoridation policy back on the agenda and decide to integrate stakeholder feedback in the formulation stage, could use some of these questions as areas to improve outcomes should it become problematic.

The final chapter will conclude the research study, highlighting implementation theory as it relates to water fluoridation policy in design and outcomes. The conclusions and recommendations will also discuss some of the alternative models and potential challenges in moving away from water fluoridation policy in this country. It will then suggest further research opportunities moving forward over the next decade and beyond.

Chapter 6: Conclusion

Summary

The history of water fluoridation, from initial discovery of the Colorado brown stain to developing a recommendation to inject water with fluoride compounds to derive a public health outcome, is important to understanding the past and future of this policy area. The policy has also been one of contention in the United States, as individuals have brought suit aimed at stopping community water fluoridation practice. Time and again outcomes point in the direction of the utility of public health measures and the right for communities to fluoridate if they choose to do so. In this national environment, however, understanding the possible challenges to implementation and policy are critical. This research explores these issues.

The Federal Panel on Community Water Fluoridation's policy recommendation was made in 2015. This recommendation changed the way the optimal water fluoridation level was determined in the United States. This research provides evidence for potential future challenges as a result of this policy decision and decision-making process. While it is difficult to foresee how this policy recommendation will be realized in the United States over the next ten to twenty years, the policy research performed could potentially reveal approaches to analyzing this policy in the future from theoretical and methodological perspectives. Historically, the amount of time for water fluoridation policy recommendations to move from policy adoption back onto the policy agenda was approximately fifty years. The first policy recommendation occurred in 1962 after years of experiments and research into optimal fluoridation level ranges to allow for different communities and geographies to customize their fluoridation solutions. In 2015, the recommendation moved from a range of optimal fluoride levels to a fixed level for all.

The central research question highlights the potential challenges coming from a centralized policy recommendation in a decentralized policy environment. It can be argued that US fluoridation policy is implemented in a decentralized decision-making environment because this has evolved as the most effective way to achieve an optimal policy outcome. This policy began in cities across the country, growing in scope to cover the majority of water systems across the United States. As already noted, individual water utilities and cities have their own characteristics regarding water quality and treatment and a policy range has appeared to meet the needs of the majority of communities over time. A policy mandate has the potential to challenge the ability of communities to meet this rigid metric. In this sense, the 2015 recommendation has the potential to impact policy implementation and outcomes.

Literature relevant to the policy recommendation followed the Federal Panel's research approach, highlighting various research studies and publications significant in making a scientific policy recommendation. The literature provided guidance to the new policy recommendation which was based on scientific consensus. The typology provided in the literature review reveals that there are potential research gaps in the area of water fluoridation policy in making a centralized policy recommendation in a decentralized policy environment. While the old policy range allowed for local decision-making, a centralized recommendation moves this decision from local to central policy decision-makers. The perception and understanding of this centralizing recommendation was only partially explored and not until the recommendation was released for review. Engaging stakeholders who are tasked with implementation is one research gap addressed in this research. Within this gap are significant areas of research which would have potentially informed the formulation process but also potentially lead to better outcomes in implementation. There are questions left unanswered about the feasibility of hitting the 0.7

mg/L mark consistently and if water managers view the recommendation as a ceiling thus underfluoridating which can be broadly understood with an understanding of the policy environment. The recommendation has no federal authority or enforcement to incentivize the desired outcome. Additionally, as this research has shown, there were viable alternatives such as salt or milk fluoridation which were not included in the review.

Policy actors were identified and discussed in order to understand the policy at all levels of the federalist environment in which this policy exists. Understanding policy actors is of increasing importance in understanding policy change due to collective action (Sabatier, 1999). Applying Coleman's theory of exchange, purposive action, and structures of social action (Coleman, 1998), policy actors and actions were explored in great detail to understand who the actors are and the structure of water fluoridation formulation, policy decision-making, and implementation. In this policy area at the local level, water consumers have transferred their self-interests to water managers because of scale, affordability, and practicality but are still the principal within the principal-agent understanding of basic community water services. At the state level, the primary interaction of actors would be between the state health agencies and the water managers and the state agencies and the federal health agencies. At the federal level, the CDC is charged with monitoring this policy using the WFRS. Within the context of the policy process, which consists of federal level policy experts, the policy elites who are tasked with policy recommendations in water fluoridation policy are dominant. Principal-agent theory of behavior helped describe the complexities involved with the amount of actors and their possible interactions at all levels. In the end, two sets of actors in this policy area are most significant, the policy elites and the water managers. The policy elites of fluoridation policy hold decision-making power and are the actors that will formulate policy alternatives at this point in time. Water managers are tasked with interpreting the policy recommendation after adoption, and depending on state, will self-determine if they implement the recommendation.

It was with this in mind that a theoretical framework cycle was developed in order to explain and potentially predict future outcomes for this policy. The Adaptive MS-ACF Policy Cycle "Walker Framework" could be an area of future research, with some slight modifications made in order to perfect its prediction capabilities or application outside of water fluoridation policy. This would likely require generalizing the theory as it is highly focused. This is a contribution to policy theory as not only is there a call for grand theory, but better theories overall (Sabatier, 1999). There are potential problems developing and applying grand theories to policy as the environment is complex with hundreds of actors involved (Sabatier, 1999) and in the case of water fluoridation policy, there are thousands of actors involved. The Walker Framework would most likely not even fall within the context of mid-range policy theories as it focuses on the policy process involved in water fluoridation decision-making. Water fluoridation policy is different in many ways from more traditional policy processes, however this theory could help predict future outcomes in this policy area despite the complexities involved.

Implementation and stakeholder engagement theories were explored to effectively set the stage for the policy formulation and implementation pieces of research. Incorporating actors at all levels of the policy environment is increasingly important in policy implementation outcomes (Pressman, Wildavsky, 1984) which in a policy area such as water fluoridation is critical especially with a centralized policy in a decentralized policy environment. Stakeholder engagement is a contemporary research area which can potentially improve policy outcomes by, depending on the amount of stakeholder involvement, allowing those who have a stake in the policy have input in the process. While the new policy recommendation comment period could be seen as a notification or advisory style, perhaps a consultative or decision-making style would be more appropriate (Cowie, Borrett, 2005). As water fluoridation policy is somewhat of a hybrid natural resource and public health policy area and stakeholder engagement is still a relatively new development in policy decision-making, this could help explain the style used for this process.

The research endeavor utilized a mixed methods approach with both a quantitative and qualitative component to explore the research gaps identified. The quantitative component examined water fluoridation levels using CCRs which provide transparency to the public about what is in their drinking water. Using inferential and one sample t-testing, water fluoridation implementation over the past years revealed that the mean fluoridation level and variability in levels have fallen since the recommendation was first announced and finalized. There are some groups still not receiving the health benefits of this policy in cities that do not fluoridate and in some rural areas. It does appear that the recommendation is likely being met, but there was enough evidence to suggest close monitoring of implementation for the next decades to ensure outcomes. The qualitative component revealed street-level bureaucrat perceptions of the policy recommendation and even possible areas of policy research. While the qualitative research is not generalizable to the water manager population broadly, it can perhaps spur additional dialogue between policy makers and their front-line counterparts in the future. Overall general results were that: water managers felt engaged in the process and that the AWWA had say in the policy decision, that the recommendation can be met and policy elites understand complexities involved in water treatment, a slight preference for the status quo of looking to the state for policy recommendations, and mixed results for exploring alternate policy options, policy equitability, and whether consumers should be allowed to opt-out. It can certainly create some discussion about where the policy research goes from here, and a possible research agenda moving forward.

Discussion

Now that this major policy change has been made, are there opportunities for other changes to United States fluoridation policy. For example, is the time ripe for utilizing alternate strategies to meet this policy objective; whether it be fluoridated salt or milk, these could be alternate methods to meet the requirement. Besides understanding who the intransigent policy elites are in charge of this policy area, there are other constraints in moving to a new national model. As was mentioned earlier, this is a state issue and there is solid case law on related state and community water fluoridation. It is possible that if milk fluoridation programs were considered, it may not change the decentralized nature of the policy. However, fluoridated milk or fluoridated salt would still need to acquire FDA approval.

One of the takeaways from this policy recommendation is there appears to be a continued commitment to decentralized implementation. Despite making a centralizing policy recommendation with central policy options available to achieve this outcome, community water fluoridation remains the model of choice to achieve the policy outcome. This could be attributed to path dependence, which in its simplest definition is that policy history matters and what has been the policy reality in the past limits future policy possibilities (Pierson, 2000). Water fluoridation is firmly entrenched into American health policy and changing the approach to this policy moving forward is difficult. Does this history limit future policy options for the Federal Panel on Community Water Fluoridation? Even the name of the panel assigned to making policy recommendations displays this path dependent concept.

In applying the "Walker Framework" on water fluoridation policy, the Adaptive MS-ACF Policy Cycle could help predict future policy recommendations. If evidential consensus mounts in the coming decades and water fluoridation policy comes back on the agenda for various possible reasons, such as continued overexposure, implementation problems, or other policy problems, what might the next policy recommendation look like? Assuming a path dependent reality, the water fluoridation level could be lowered to the lowest possible setting to derive the dental benefit, identified by the WHO to be 0.5 mg/L (WHO, 2004). As discussed, belief structures are very important in the context of the ACF component of this framework and it would be realistic to assume that once committed to this policy model it would be difficult to move away from its continued use. Assuming that the Federal Panel can break away from this path dependent commitment to the community water fluoridation practice model, there are other evidentiary models that are practiced across the world today that could be considered.

Based on the literature and research the most likely scenario if the Federal Panel were to move to a more centralized policy to reflect the newest recommendation would be considering the use of salt fluoridation. Salt fluoridation has been practiced in Germany and other countries for over twenty-five years as referenced in chapter four. There is a well-established body of data for use of fluoridated salt to derive similar outcomes and as Germany is a federalist system the application to the United States remains a viable possibility. Additionally, salt fluoridation opens the possibility for consumers to opt-out of fluoridation policy (Jones et al, 2005). This possibility could be a potential sticking point for adoption, however, but some contemporary policy models include opt-out components. If this were to occur it would require the formulation and adoption of this policy by the Federal Panel, followed by FDA approval, and then to production alongside unfluoridated salt alternatives. Jones et al provide evidence from contemporary studies in 2005 that the optimal concentration would be around 250 mg/kg (Jones et al, 2005).

A less likely scenario, but one that has been explored in the United States would be milk fluoridation programs (Bánóczy et al, 2009). The benefit of a program of this nature is that it would focus on children when dental caries policy is at its most important and the greatest outcomes are achieved (Bánóczy et al, 2009). Additionally, this would allow for opt-out possibilities by parents similar to vaccination policy. The negatives would be that only children would be a part of the program and adults would miss out on any continued dental benefits beyond childhood.

There are already other methods of opting in to fluoride use for dental caries prevention in place in the U.S. Fluoride supplements are available to purchase for people living in areas which do not fluoridate or are underexposed to fluorides. Additionally there is fluoridated baby water to make powdered formula bottles available in grocery stores. There are ways to opt-in to fluoridation, but relatively few ways to opt-out if the community one lives in fluoridates its water source to meet the recommendation. Additionally, the costs involved with building and maintaining water infrastructure make it impractical to have water systems deliver two kinds of treated water, one with and one without added fluoride.

In the end this research illustrates that it will be in the hands of the policy elites, in this case, the Federal Panel to decide the future direction of this policy in the United States. Earlier policy changes indicate that before future policy changes, policy elites will need a decade or more of data regarding implementation and policy coverage in combination with dental caries trends and fluorosis level trends. If fluorosis levels drop and if caries trends continue to remain positive, community water fluoridation practice may not come back to the policy agenda. If at some point data points to a potential problem, some of these predictions could become policy realities in the future.

Recommendations

Despite dominance at the national level in both research and policy-making, and despite well-resourced, strong statewide and local advocacy, there are still opportunities at the local level for self-determination around this policy issue. While there are few examples of successful rejection of this policy, a good future research question is why are some areas more successful than others at keeping unfluoridated water? There are examples of major metropolitan areas that reject fluoridation policy. While this is not the focus of this paper, exploring this question might be helpful in future research and in understanding how collective decision-making around water fluoridation in this country takes shape. Future research might also benefit from the application of Sabatier's work on coalition building around community water fluoridation. Additional research could be in generating maps of fluoridation gaps to better understand pockets of non-fluoridation and whether that is based on political cause or potential urban versus rural issues in fluoridation delivery. These gaps could lead to studies determining if these groups have any difference in DMFT rates than those in fluoridated communities which would add to the research area.

Given the inherent variability in policy making in this environment, it is important that there is ongoing self-reporting using the water fluoridation reporting system and monitoring. Another possible area of future research is if fluoridating at the treatment facility and reporting to the fluoridation reporting system that water is fluoridated to 0.7 mg/L equals 0.7 mg/L at any given time. The WFRS, as a self-reporting system, does not include sampling results such as those in CCRs as understood in this research. Is it as simple as setting the injection system to 0.7 mg/L and getting a sample of 0.7 mg/L every time? As reported in the policy recommendation, as of 2011 68% of the population on water system drinking water were receiving the optimal amount of 0.7 mg/L and 28% were receiving water over 1 mg/L (FR, 2015). Monitoring the 28% receiving over or less than optimally fluoridated water will be the main concern moving forward. Future research will also need to follow caries and fluorosis trends as was done before the recommendation in countries using both water fluoridation and salt fluoridation or other alternative methods of achieving caries reduction.

As the recommendation is understood to be credibly committed to by the panel, it is assumed that water systems will need to respond to future discrepancies. As mentioned in prior chapters, there could be ongoing questions related to the policy recommendation even though with a flat 0.7 mg/L as the recommendation it is hard to conceive where the questions would be. Another area of future research may be to review different states individual responses. As was mentioned in the Kentucky code reference, a new range was written into law and enforced, instead of the fixed 0.7 mg/L recommended level. Although the optimal recommendation in the code reflects this number this remains different than the national recommendation.

States will continue to be the main enforcement bodies and seem to be responsive to the recommendation and have a plan in place to advise water systems on the policy recommendation. As mentioned in an earlier chapter, there are some concerns about local interpretation of the policy recommendation, but given time the profession should move towards compliance. In states where compliance is not mandatory or if local ordinances are the standard then this approach could become problematic. However, the results of the survey point to the ability of managers to meet the recommendation. Certainly the professional water associations will be a critical resource for continuing education in this policy area. A circular exchange of information between levels of the federalist system will only improve implementation outcomes.

It is difficult to predict how this policy will evolve in the future. Certainly for the foreseeable future, the United States will remain a community water fluoridation model country. If at some point in the future this policy is put back on the policy agenda, there are possible paths for future fluoridation policy identified in this research. At that point in time there may be new technology which is currently unavailable, but the policy cycle should continue to hold and will be instrumental in future policy recommendations and changes.

APPENDICES

Appendix A: Fluoridated Water Code for South Carolina

"S.C. Code of Regulations 61-58.7 Operation and maintenance
Where fluoride is added to the water, the following shall apply: (a) the fluoride content of the water shall be maintained between 0.8 and 1.2 mg/l; (b) finished water shall be analyzed daily for fluoride content; (c) should a public water system cease fluoridating for any reason, the South Carolina Department of Health and Environmental Control shall be notified immediately; and (d) a public water system which fluoridates must notify their service population and all local dental and public health practices prior to ceasing fluoridation. B. General Requirements for Operation and Maintenance of Public Water Systems. (11) Where fluoride is added to the water the following shall apply: (a) The fluoride content of the water shall be maintained between eight-tenths (.80) and one and two-tenths (1.20) milligrams per liter. (b) Finished water shall be analyzed daily for fluoride content in accordance with methodology specified in Section C(17) of R.61-58.5. (c) Should a public water system cease fluoridating for any reason the Department shall be notified immediately. (d) A public water system which fluoridates must notify their service population and all local dental and public health practices prior to ceasing fluoridation." (SC code 61-58.7)

"S.C. Code of Regulations 61-58.5 Maximum contaminant levels in drinking water.
B. Maximum Contaminant Levels for Inorganic Chemicals (1) The Maximum Contaminant Levels (MCLs) for inorganic contaminants specified in R.61-68.5(B)(2) shall apply to all public water systems. Compliance with maximum contaminant levels for inorganic chemicals are calculated pursuant to Section (C) below: (2) The maximum contaminant levels for inorganic chemicals are as follows: (Table omitted - contains the following information: Contaminant: Fluoride Level (mg/l): 4.0)) . . . R. Secondary Maximum Contaminant Levels. (1) The secondary maximum contaminant levels are applicable to all public water systems. (2) The secondary maximum contaminant levels are as follows: (Table omitted, but contains the following information: Contaminant: Fluoride Level: 2.0 mg/l) . . . (4) Community water systems that exceed the secondary MCL for fluoride, as determined by the last single sample taken in accordance with the requirements of these regulations, shall send the notice described in paragraph (5) of this section, to: (1) all existing billing units, (2) all new billing units at the time service begins, and (3) the Department. (5) The public notice that shall be used by systems which exceed the secondary MCL for fluoride shall contain the specific language outlined in R.61-58.6.E(8), and no additional language except as necessary to complete the notice." (SC code 61-58.5)

"S.C. Code of Regulations 61-58.6 Reports, record retention and public notification

This regulation includes the special notice for exceedance of the SMCL for fluoride. Public notice must be provided as soon as practical but no later than 12 months from the day the water system learns of the exceedance. A copy of the notice must also be sent to all new billing units and new customers at the time service begins and to the State public health officer.

TABLE 1: VIOLATION CATEGORIES AND OTHER SITUATIONS REQUIRING A TIER 3 PUBLIC NOTICE . . . (8) Special Notice for Exceedance of the SMCL for Fluoride. (a) When is the special notice to be given? Community water systems that exceed the fluoride secondary maximum contaminant level (SMCL) of 2 mg/l as specified in R.61-58.5.R (determined by the last single sample taken in accordance with R.61-58.5.C, but do not exceed the maximum contaminant level (MCL) of 4 mg/l for fluoride (as specified in R.61-58.5.B), must provide the public notice in paragraph (c) of this section to persons served. Public notice must be provided as soon as practical but no later than twelve (12) months from the day the water system learns of the exceedance. A copy of the notice must also be sent to all new billing units and new customers at the time service begins and to the State public health officer. The public water system must repeat the notice at least annually for as long as the SMCL is exceeded. If the public notice is posted, the notice must remain in place for as long as the SMCL is exceeded, but in no case less than seven (7) days (even if the exceedance is eliminated). On a case-by-case basis, the Department may require an initial notice sooner than twelve (12) months and repeat notices more frequently than annually. (b) What is the form and manner of the special notice? The form and manner of the public notice (including repeat notices) must follow the requirements for a Tier 3 public notice in paragraphs (4)(c) and (d)(i) and (d)(iii) of this section. (c) What mandatory language must be contained in the special notice? The notice must contain the following language, including the language necessary to fill in the blanks: “This is an alert about your drinking water and a cosmetic dental problem that might affect children under nine years of age. At low levels, fluoride can help prevent cavities, but children drinking water containing more than 2 milligrams per liter (mg/l) of fluoride may develop cosmetic discoloration of their permanent teeth (dental fluorosis). The drinking water provided by your community water system [name] has a fluoride concentration of [insert value] mg/l. Dental fluorosis, in its moderate or severe forms, may result in a brown staining and/or pitting of the permanent teeth. This problem occurs only in developing teeth, before they erupt from the gums. Children under nine should be provided with alternative sources of drinking water or water that has been treated to remove the fluoride to avoid the possibility of staining and pitting of their permanent teeth. You may also want to contact your dentist about proper use by young children of fluoride-containing products. Older children and adults may safely drink the water. Drinking water containing more than 4 mg/L of fluoride (the U.S. Environmental Protection Agency's drinking water standard) can increase your risk of

developing bone disease. Your drinking water does not contain more than 4 mg/l of fluoride, but we're required to notify you when we discover that the fluoride levels in your drinking water exceed 2 mg/l because of this cosmetic dental problem.” (SC code 61-58.6)

Appendix B: Fluoridated Water Index of Codes and Ordinances by State, Federal City, and Territory

Alabama: No state law or state regulation, local ordinances are unique, ADEM monitors
Alaska: Alaska Admin. Code Title 18 § 80.315. Inorganic chemical sampling requirements
Alaska Admin. Code Title 18 § 80.340. Examination of water: owner or operator requirements
Alaska Admin. Code Title 18 § 80.355. Reporting Requirements (Adopted Oct. 1, 1999)
Arizona: Ariz. Admin. Code R9-23-101.
Arkansas: Ark. Admin. Code 007.10.38-III
California: Cal. Code Regs. Title 22 § 64400.42. Fluoridation
Cal. Code Regs. Title 22 § 64433. System Requirements and Exemptions
Cal. Code Regs. Title 22 § 64433.2. Optimal Fluoride Levels
Cal. Code Regs. Title 22 § 64433.3. Monitoring and Compliance-Fluoride Levels
Cal. Code Regs. Title 22 § 64433.5. Fluoridation System
Cal. Code Regs. Title 22 § 64433.7. Recordkeeping, Reporting, and Notification for Water Systems Fluoridating
Cal. Code Regs. Title 22 § 64433.8. Fluoridation System Operations Contingency Plan
Cal. Code Regs. Title 22 § 64434.
Colorado: No state law or state regulation, local ordinances are unique, DPHE monitors
Connecticut: Conn. Agencies Regs. § 19-13-B102. Standards for quality of public drinking water
Delaware: 16 Del. Admin. Code § 4462-6.0. Inorganic and Organic Chemical Requirements
Washington D.C.: purchases treated water from the Army Corps Washington Aqueduct (Federal Agency/Federal city)
Florida: Fla. Admin. Code Ann. r. 62-555.325. Fluoridation
Georgia: Ga. Comp. r. & Regs. R. 290-5-19-.01. Fluoridation
Hawaii: No state law or state regulation, local ordinances are unique
Idaho: Idaho Admin. Code 58.01.08.552 Facility and Design Standards: Operating Criteria for Public Water systems
Illinois: Ill. Admin. Code Tit. 35 § 611.125. Fluoridation Requirement
Ill. Admin. Code Tit. 35 § 611.130 Special Requirements for Certain Variances and

Adjusted Standards
Indiana: Ind. Admin. Code Tit. 327, r. 8-1-1 Community water system; fluoridation; phosphate additives
Iowa: Iowa Admin. Code r. 641-20.(1-9)
Kansas: No state law or regulation, local ordinances are unique, DHAE
Kentucky: 902 Ky. Admin. Regs 115:010. Water fluoridation for the protection of dental health
902 Ky. Admin Regs. 115:020. Enforcement of Water Fluoridation Program
Louisiana: La. Admin. Code Tit. 48, § 1101 Definitions
La. Admin. Code Tit. 48, § 1303. Background and Purpose
La. Admin. Code Tit. 48, § 1305. Requirements for Fluoridation of a Public Water System
La. Admin. Code Tit. 48, § 1307. System Requirements
La. Admin. Code Tit. 48, § 1309. Monitoring and Compliance -Optimum Fluoride Levels
La. Admin. Code Tit. 48, § 1311. Recordkeeping and Reporting
La. Admin. Code Tit. 48, § 1313. Funds Allocation
La. Admin. Code Tit. 48, § 1315. Requirement for Continued Operation
Maine: Code Me. R. 10-144 Ch. 228, § 1 General Provisions
Code Me. R. 10-144 Ch. 228, § 2 Definitions
Code Me. R. 10-144 Ch. 228, § 3 Fluoridation implementation
Code Me. R. 10-144 Ch. 228, § 4 Approved chemicals
Code Me. R. 10-144 Ch. 228, § 5 Fluoride control levels
Code Me. R. 10-144 Ch. 228, § 6 Design standards
Code Me. R. 10-144 Ch. 228, § 7 Safety
Code Me. R. 10-144 Ch. 228, § 8 Reporting
Code Me. R. 10-144 Ch. 228, § 9 Enforcement
Maryland: Md. Regs. Code 26.04.01.20 Public Notification of Variances, Exemptions, and Noncompliance with Standards.
Massachusetts: Mass. Regs. Code tit. 310, § 22.06 Inorganic chemical maximum contaminant levels, monitoring requirements and analytical methods
Mass. Regs. Code tit. 310, § 22.06C Compliance with secondary maximum contaminant level and public notification for fluoride
Mass. Regs. Code tit. 310, § 22.16 Public notification requirements
Michigan: Mich. Admin. Code r. 325.10401a General public notification requirements
Mich. Admin. Code r. 325.10604c MCL for inorganic chemicals.
Mich. Admin. Code r. 325.10404e: Tier 3 public notice; form, manner, and frequency of notice
Mich. Admin. Code r. 325.10408a: Special notice when fluoride level is above 2.0 mg/l
Mich. Admin. Code r. 325.10420: Annual water quality reporting; contaminants for vulnerable subpopulation.

Minnesota: Minn. R. 4720.0030 Fluoridation.
Minn. R. 4720.3960 Chemical storage.
Mississippi: Miss. Admin. Code 15-6-6:100 General Provisions
Miss. Admin. Code 15-6-6:101. Adjusted Fluoridated Water System Requirements
Miss. Admin. Code 15-6-6:102. Optimal Fluoridation Requirements.
Miss. Admin. Code 15-6-6:103. Compliance.
Miss. Admin. Code 15-6-6:104. Authority to Request Raw Water Sample.
Missouri: Mo. Code Regs. Ann. tit. 10, § 60-4.070 Secondary Contaminant Levels and Monitoring Requirements
Montana: Mont. Admin. R. § 17.38.230 Fluoridation
Nebraska: Neb. Admin. Code tit. 179, § 001 Certification
Neb. Admin. Code tit. 179, § 002 Application for certification
Neb. Admin. Code tit. 179, § 003 Operation
Neb. Admin. Code tit. 179, § 004 Revocation of certificate
Nevada: Nev. Admin. Code 445A,65975 "Fluoridation" defined.
Nev. Admin. Code 445A.6682 Fluoridation
New Hampshire: N.H. Code Admin. R. Ann. Env-Dw 713.06 Annual fluoride public notice for secondary MCL exceedance
New Jersey: N.J. Admin. Code tit. 7, § 7:10-7.2 Recommended upper limits and optimum ranges for physical, chemical and biological characteristics in drinking water
N.J. Admin. Code tit. 7, § 7:10-11.15 Miscellaneous treatment processes
New Mexico: No state law or regulation, local ordinances are unique
New York: N.Y. Comp. Codes R. & Regs. tit. 10, § 5-1.24 Approval of fluoridation of public water systems
North Carolina: N.C. Admin. Code tit. 15A, r. 18C.1401 Policy
N.C. Admin. Code tit. 15A, r. 18C.1402 Formal Application
N.C. Admin. Code tit. 15A, r. 18C.1404 Feeding equipment
N.C. Admin. Code tit. 15A, r. 18C.1405 Protection of operators
N.C. Admin. Code tit. 15A, r. 18C.1406 Control of treatment process
N.C. Admin. Code tit. 15A, r. 18C.1407 Approval may be rescinded
North Dakota: No state law or regulation, local ordinances are unique
Ohio: Ohio Admin. Code § 3745-82-02 Secondary maximum contaminant levels.
Ohio Admin Code § 3745-82-03 Monitoring for compliance with secondary maximum contaminant levels.
Oklahoma: Okla. Admin. Code. § 252:626-9-12. Fluoridation.
Oregon: Or. Admin. R. 333-061-0030 Maximum contaminant levels and action levels.
Or. Admin. R. 333-061-0042 Public Notice.
Or. Admin. R. 333-061-0045 Variances.
Or. Admin. R. 333-061-0085 Supplemental Fluoridation.

Or. Admin. R. 333-061-0097 Adverse Health Effects Language.

Pennsylvania: 25 Pa. Code § 109.202

Puerto Rico: 12 P.R. Laws. Ann. § 262. Control and reduction of incidence of dental caries

12 P.R. Laws. Ann. § 263 Protection and maintenance of oral health

12 P.R. Laws. Ann. § 264 Definitions

12 P.R. Laws. Ann. § 265 Regulation of fluoride levels

12 P.R. Laws. Ann. § 266 Activation and expansion plan to add fluoride

12 P.R. Laws. Ann. § 267 Stages of implementation

12 P.R. Laws. Ann. § 268 Advice of professionals

12 P.R. Laws. Ann. § 269 Education about the benefits of fluoride

12 P.R. Laws. Ann. § 270 Penalties

Rhode Island: R.I. Code R. 31-7-7:16.0. Community water system requirements.

R.I. Code R. 31-7-7 Appendix B. to § 16.8 Standard health effects language for public notification

R.I. Code R. 31-7-7 Appendix A to § 16.10

South Carolina: S.C. Code of Regulations 61-58.7 Operation and maintenance.

South Dakota: S.D. Admin. R. 74:04:01:02 Written approval required to implement fluoridation

S.D. Admin. R. 74:04:01:03. Required minimum fluoride levels -- Reduction of natural excessive levels

S.D. Admin. R. 74:04:01:04. Equipment construction, installation, and operation

S.D. Admin. R. 74:04:01:05. Daily testing required

S.D. Admin. R. 4:04:01:06. Samples to be tested in Pierre-Frequency

S.D. Admin. R. 74:04:01:07. Daily records required

Tennessee: Tenn. Comp. R. & Regs. 1200-05-01-.17 Operation and maintenance requirements

Tenn. Comp. R. & Regs. 1200-05-01-.19 Notification of customers

Texas: No state law or regulation, local ordinances are unique

Utah: Utah Code Ann. § 309-220 Monitoring and water quality: public notification requirements

Utah Code Ann. § 309-400 Water system rating criteria

Utah Code Ann. 309-535 Facility Design and operation: miscellaneous treatment methods

Vermont: Vt. Code R. 16-3-500:7.3. Fluoridation

Virgin Islands: 19 V.I. Code Ann. § 4201 Fluoridation required; amounts

19 V.I. Code Ann. § 4202 Exceptions

19 V.I. Code Ann. § 4203 Responsibility for administration and enforcement

19 V.I. Code Ann. §4204 Penalty

Virginia: 12 Va. Admin. Code 5-590-930
Washington: Wash. Admin. Code 246-290-460. Fluoridation of drinking water.
West Virginia: W. Va. C.S.R. § 64-77-6. Treatment
Wisconsin: Wis. Admin. Code s NR 811.51. Fluoridation
Wyoming: Wyo. Rules and Regulations ENV WQ Ch. 12 § 10. Treatment.

Appendix C: Case Law Regarding Water Fluoridation

Example 1: Froncek and others, Appellants, v. City of Milwaukee (1951)

PROCEDURAL POSTURE: Plaintiffs, citizens of a city, appealed a judgment of the Circuit Court for Milwaukee County (Wisconsin), which denied an injunction sought against defendants, a city and its officers, preventing the city from adding fluoride to its municipal water supply. The trial court granted summary judgment in favor of defendants. OVERVIEW: The city passed various resolutions in which it decided to treat its water supply with fluorides for the purpose of reducing the incidence of dental caries in children. The citizens filed an action seeking an injunction prohibiting the city from adding the fluoride, asserting that the issue of consuming fluoride was one of private health and that the city exceeded its police power in enacting a resolution allowing the entire municipal water supply to contain fluoride. The citizens also argued that Wis. Stat. § 97.27(1), which prohibited the manufacture or sale of any food product containing fluoride, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.S. § 371, precluded the city from adding the fluoride to the water supply. On appeal, the court held that § 97.27(1) and the federal act did not apply to either municipal water supplies or those private food manufacturers and processors who used the municipal water supply in their preparation of food products. The health of the city's children was of vital interest and great importance and the resolution bore a real, substantial, and reasonable relation to the health of the city. OUTCOME: The court affirmed the trial court's judgment. (LexisNexis)

Example 2: Alice Schuringa et al., Appellants, v. The City of Chicago (1964)

PROCEDURAL POSTURE: Plaintiff citizens sought review of a decision from the Superior Court of Cook County (Illinois), which dismissed the citizens' compliant against defendants, city and officials, to enjoin defendants from fluoridating the city's water supply. The citizens appealed directly to the court for review because constitutional questions were involved. OVERVIEW: The city passed a resolution that declared that the fluoridation of the water supply was in the interest of the public health and that steps for the introduction of fluoride in a concentration adequate for safety and in accordance with the regulations be undertaken. On appeal, the court affirmed the trial court's judgment in favor of defendants. The court found that a police measure, to be beyond the pale of constitutional infirmity, must bear a reasonable relation to the public health or other purpose sought to be served, and the means must be reasonably necessary and suitable for the accomplishment of such purpose. The court then determined from all of the evidence in the record, as well as the scientific, professional, and legal authorities, that there appeared to be extraordinary accord that fluorides acted to prevent and reduce tooth decay, and that artificial fluoridation to the extent proposed by the city would not, presently or cumulatively, result in harmful systemic effects. The court reasoned that evidence that the fluoridation caused harm was debatable. Therefore, the legislative judgment prevailed. OUTCOME: The court affirmed in favor of defendants in the action by the citizens to enjoin defendants from fluoridating the city's water supply. (LexisNexis)

Example 3: Carlton Hall, Appellant, v. Mayor Lester Bates, William H. Tuller, William C. Ouzts, R.E.L. Freeman, Hyman Rubin, Individually and collectively and as City Council of the City of Columbia, a municipal corporation, and Cary Burnett, City Manager (1966)

PROCEDURAL POSTURE: Plaintiff resident appealed an order of the circuit court (South Carolina), which granted judgment in favor of defendant city in an action for an injunction to prevent the fluoridation of the city water supply. The resident contended that the fluoridation unduly infringed upon his individual liberty under S.C. Const. art. I, § 5 and U.S. Const. amend. XIV, and that it violated his equal protection rights. OVERVIEW: After the state board of health filed a rule regulating the addition of fluoride to public water supplies, the city held a public hearing and concluded that its water supply should be fluoridated. The resident filed an action for an injunction to prevent the city from fluoridating the water supply. The resident contended that fluoridation was not beneficial and was in fact harmful to his arthritic condition. The trial court granted judgment in favor of the city. The resident appealed and contended that fluoridation unduly infringed upon his individual liberty under S.C. Const. art. I, § 5 and U.S. Const. amend. XIV, and that it violated his equal protection rights. The court affirmed and held that the entire weight of authority in the country was against the resident, as it had been shown that after years of research and study, fluoridation of water supplies was of tremendous health benefits to the public. The court found that the U.S. Supreme Court had repeatedly denied certiorari in such fluoride cases for lack of a substantial federal question. The court held that the state and city had proper police powers to protect the public health, and such action was not unconstitutional. OUTCOME: The court affirmed the judgment of the trial court. (LexisNexis)

Appendix D: Stakeholder Engagement Survey

Information About Being in a Research Study
Clemson University

Community Water Fluoridation Stakeholder Survey

Dr. Lori A. Dickes and Thomas C. Walker III, PhDc are inviting you to take part in a research study. Dr. Dickes is a faculty member at Clemson University. Thomas C. Walker III is a student at Clemson University, running this study with the help of Dr. Dickes. The purpose of this research is regarding the new national policy recommendation for community water fluoridation. On April 27, 2015, the U.S. Department of Health and Human Services released the final Public Health Service (PHS) recommendation for the optimal fluoride level in drinking water to prevent tooth decay. The new optimal fluoride level recommendation is 0.7 mg/L. The new optimal level replaces the original optimal range of 0.7 mg/L – 1.2 mg/L signaling a change in policy implementation. This survey is intended to understand the implications of this change at the local level. Your participation is appreciated and if you are interested in the final results we would be happy to provide those.

Your part in the study will be to answer, to the best of your ability, the questions regarding the new national Community Water Fluoridation policy recommendation and its impact at the local level.

The survey will take approximately 5 minutes.

We do not know of any risks or discomforts to you in this research study.

We do not know of any way you would benefit directly from taking part in this study. However, this research may help us to understand the implications for local water utilities to implement the new national recommended water fluoridation level.

All information collected is confidential. There is no personal identification associated with the online survey. All results are aggregated and will not identify anyone individually. All information gathered from this survey will be stored on a secure computer.

You do not have to be in this study. You may choose not to take part and you may choose to stop taking part at any time. You will not be punished in any way if you decide to not be in the study or to stop taking part in the study.

If you have any questions or concerns about this study or if any problems arise, please contact

Dr. Lori Dickes at Clemson University at 864-656-7831 or Thomas C. Walker III at 864-656-7135.

If you have any questions or concerns about your rights in this research study, please contact the Clemson University Office of Research Compliance (ORC) at 864-656-0636 or irb@clemson.edu. If you are outside of the Upstate South Carolina area, please use the ORC's toll-free number, 866-297-3071.

Clicking on the "agree" button indicates that:

• You have read the above information

• You voluntarily agree to participate

• You are at least 18 years of age

You may print a copy of this informational letter for your files.

1. For demographic purposes, please choose one answer that best fits your community water system.

○ Urban

○ Rural

2. As a stakeholder in Community Water Fluoridation programs, water manager's input was considered in adopting the new fluoridated water recommendation.

○ Strongly Agree

○ Agree

○ Disagree

○ Strongly Disagree

○ Do Not Know

3. The American Water Works Association (AWWA) had input into adopting the 0.7 mg/L fluoridated water level.

○ Strongly Agree

○ Agree

○ Disagree

○ Strongly Disagree

○ Do Not Know

4. National fluoridation policy experts involved a broad range of stakeholders in the process of adopting the new optimal water fluoridation level for the United States.

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Do Not Know

5. National fluoridation policy experts understand the complexities of delivering the new 0.7 mg/L fluoridation level to local communities.

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Do Not Know

6. Community Water Fluoridation programs can consistently deliver the newly recommended fluoridated water level of 0.7 mg/L across the United States.

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Do Not Know

7. Our community fluoridates water at 0.7 mg/L.

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Do Not Know

8. The federal government should make fluoride policy and decide fluoride limits for local water systems.

- Strongly Agree

- Agree
- Disagree
- Strongly Disagree
- Do Not Know

9. State governments should make fluoride policy and decide fluoride limits for local water systems.

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Do Not Know

10. Local water managers should be able to continue to fluoridate water at the level they deem appropriate based on local conditions.

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Do Not Know

11. Other methods of fluoridation should be explored by the federal government to achieve the same public health outcome (using fluoridated salt, milk, etc.)

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Do Not Know

12. Community Water Fluoridation programs, as they are currently implemented in this country, are equitable.

- Strongly Agree
- Agree
- Disagree

- Strongly Disagree
- Do Not Know

13. Water consumers should be allowed to opt out of community water fluoridation programs.

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree
- Do Not Know

14. VOLUNTARY: If you would like final results e-mailed to you add your name and e-mail.

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