Scientific and Technical Publication No. 615

Promoting Oral Health

The Use of Salt Fluoridation to Prevent Dental Caries

Saskia Estupiñán-Day

Pan American Health Organization
World Health Organization

W.K. KELLOGG FOUNDATION
FROM VISION TO INNOVATIVE IMPACT

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Also published in Spanish (2005),
as part of the Paltex series, with the title
Promoción de la Salud Bucodental:
La fluoruración de la sal para prevenir la caries dental

PAHO HQ Library Cataloguing-in-Publication

Pan American Health Organization
Promoting oral health: the use of salt fluoridation to prevent dental caries.
Washington, D.C: PAHO, © 2005.
(Scientific and Technical Publication No. 615)

ISBN 92 75 11615 6

I. Title II. Series

1. FLUORIDATION
2. DENTAL CARIES — prevention & control
3. ORAL HEALTH
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5. HEALTH PLANS AND PROGRAMMES

NLM WU 270

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Tool-kit for Decision-makers, Health Planners, Legislators, Epidemiologists, and Health Workers

PREFACE

An understanding of the overall development of nations shows that the solution to many of the problems that affect a population's health and, to a large extent, individuals' health cannot rely solely on expanding health care systems. All sectors, interested parties, and disciplines must apply innovative strategies to the solution if people's health—our first and foremost concern—is to be improved in the near term.

The Pan American Health Organization's Regional Oral Health Program has focused on planning and designing oral health strategies and has collaborated with the countries of the Americas to change epidemiological patterns and improve delivery systems for oral health care.

To support those who make or implement national or local oral health policies, we present *Promoting Oral Health: The Use of Salt Fluoridation to Prevent Dental Caries.* This book bears witness to the effectiveness of salt fluoridation for the mass reduction of dental caries in the population. Over time, salt fluoridation has come to be recognized as the most promising—and the most egalitarian—strategy for improving the oral health of millions in the Americas and as the key factor in changing the epidemiological profile of oral health for the Region in a relatively short period of time.

To date, 11 countries in our Region have fluoridated salt programs, and new countries continually strive to launch such programs. We offer this book to all those who are operating salt fluoridation programs or who are considering launching salt fluoridation programs, to those who implement national or local oral health policies, and to the tireless health workers who strive to improve the health of our people.

Mirta Roses Periago
Director
Pan American Health Organization

FOREWORD

For more than 60 years, the Kellogg Foundation has been a proud supporter of the Pan American Health Organization (PAHO). In collaboration with PAHO, the Foundation has done some of its most lasting and important work in Latin America and the Caribbean. And one of the proudest success stories from this fruitful partnership has been the salt fluoridation project. Because of this effort, millions of people across the region can enjoy healthier, happier, and more productive lives.

Our founder, W.K. Kellogg, was a pragmatic visionary who believed in "applying knowledge to the problems of people." The salt fluoridation program embodies this principle by combining scientific knowledge with political coordination and grassroots education. Additionally, the project was able to build on the impressive gains in water fluoridation, which resulted from an earlier Kellogg Foundation/PAHO partnership. Yet the salt fluoridation effort was distinct in its ability to deliver oral health benefits to remote locations where no municipal water supplies existed. As is true with most good ideas, the techniques pioneered by this project can be readily adapted by other nations and communities that seek to establish similar oral health programs.

Without question, there is much that can be learned from the history of this remarkable initiative. As we consider the current challenges in public and oral health that face Latin America and the world, we encourage the professionals and lay people who read *Promoting Oral Health: The Use of Salt Fluoridation to Prevent Dental Caries* to apply its lessons in as many ways and places as possible.

William C. Richardson, Ph.D.
President and Chief Executive Officer
W.K. Kellogg Foundation

INTRODUCTION

In many countries of the Americas, the high prevalence of dental caries in the population (more than 90% of schoolchildren may be affected) reflects the absence of an oral health strategy targeting the disease. And yet, the scope of this public health problem runs counter to advances many of these countries already have attained in other social indicators and in other aspects of public health.

In 1994, the Pan American Health Organization (PAHO) drafted an initial strategy to implement caries prevention programs in the Region of the Americas that relied on both water and salt fluoridation. The intention was to help create new prevention programs and strengthen existing fluoridation programs. PAHO's Regional Oral Health Program conducted a situation assessment of the countries of the Americas based on the most recent reports on caries prevalence and severity and on the existence of prevention programs. Although water fluoridation had been highly effective, the lack of adequate water distribution systems in the Region, especially in rural areas, made it difficult to implement nationwide water fluoridation programs.

In 1994, the program began to develop a strategy by evaluating experiences of countries that had launched salt fluoridation programs from the mid-1980s to the early 1990s. At that time, Costa Rica, Jamaica, and Mexico had had projects in place for more than five years. In Jamaica, the salt industry had made most of the initial investment, whereas in Costa Rica and Mexico, projects had been partially financed by the W. K. Kellogg Foundation; PAHO provided technical support to all three projects. By 1999, other countries had begun their salt fluoridation projects: Peru received financial support from the Kellogg Foundation to launch its national program in 1989; Venezuela and Colombia reported having salt fluoridation programs, but the extent of their coverage could not be determined (it is known that Venezuela's program used lower concentrations of salt than did those in other countries); Ecuador and Bolivia initiated national programs with World Bank assistance; in Uruguay, the salt industry, too, made most of the initial investment. Among salt fluoridation projects that were terminated or did not report results were a pilot program launched at the end of the 1980s by the State University of Rio de Janeiro in five municipalities in the state's northwest.

On the basis of its assessment, the Regional Oral Health Program prepared a plan that set priorities for technical cooperation needs. Initially, the plan identified six countries in which caries were widespread and/or severe, or where salt fluoridation programs were under way and would require limited additional effort. One of PAHO's objectives was that programs be multisectoral and that they include the public sector (health authorities), the private sector (the salt industry), and the financial sector (lending institutions). Also involved were the academic sector, dental associations, and other international organizations. A select group of epidemiologists, health workers, administrators, and salt production engineers have provided comprehensive technical support since the program began in 1993.

PAHO submitted a request for financial support to the W.K. Kellogg Foundation, which approved a subsidy in 1996 for implementing salt fluoridation programs in Bolivia, the Dominican Republic, Honduras, Nicaragua, Panama, and Venezuela. A year later, Kellogg approved a second subsidy to support programs in Belize and Paraguay. Meanwhile, PAHO continued to provide technical cooperation through its caries prevention projects in El Salvador, Guatemala, and Uruguay and in several Caribbean islands, including Puerto Rico. To date, Mexico and all the Central American and South American countries (except Argentina, Brazil, Chile, and French Guyana) have already begun, are maintaining, or are about to launch salt fluoridation programs.

Today, the Pan American Health Organization works to help countries advance from a less-than-optimal state of oral health and inadequate or nonexistent oral health policies, to a stage in which oral health improves and sound public health policies prevail. The promotion of fluoridated water or fluoridated salt as a mass prevention measure is a key element of this effort. Currently, salt fluoridation programs offer the best alternative, because they provide greater coverage at lower cost.

This publication has come out of the experience of national salt fluoridation programs and of 12 workshops corresponding to Phase II (first evaluation) of such programs that were held in Mexico in 1994 and in Jamaica in 1996. The book gives a historical overview of successful salt fluoridation programs; details the components, effectiveness, and benefits of the programs; and offers recommendations to health administrators who are considering establishing such a program in their countries.

We hope that it helps to confirm salt fluoridation as an effective method of preventing dental caries and encourages its application through the world. As programs continue to be developed in the Region, PAHO will share information and knowledge with the public health community as a way to improve the dental health of the Region's population.

Dr. Saskia Estupiñan-Day
Regional Advisor for Oral Health
Pan American Health Organization

ACKNOWLEDGMENTS

Over the past 12 years, the Pan American Health Organization (PAHO), with strong and ongoing support from the W.K. Kellogg Foundation, developed the foundation for launching and running salt fluoridation programs in the Region of the Americas. During these years, PAHO came up with strategies to improve the monitoring of national salt fluoridation programs, and fostered the development of knowledge in this regard and its transfer through technical cooperation. A significant part of this work was made possible by the support of the W.K. Kellogg Foundation. PAHO's and the Foundation's joint leadership and initiatives have been decisive in the success of salt fluoridation in the Americas. The development of modern dentistry and its progress in Latin America and the Caribbean is directly tied to the W. K. Kellogg's efforts—it is the single major philanthropic institution that has continually supported the advancement of oral health in the Region.

Dr. Herschel S. Horowitz' contribution deserves special mention, and he has played a vital and special role in preparing this book. His knowledge about caries prevention and fluorides, his vast understanding of dental public health, and his dedication to the field have brought better oral health to millions of Latin Americans and Caribbeans. Dr. Horowitz' pioneered the implementation of fluoridation programs and he remains as one of the most outstanding dental public health scientists of the 20th century.

Special thanks also go to all those who contributed in some way to create this publication. We are especially grateful to the ministries of health, dental programs, and the salt industry in the countries of the Americas, as well as to Eugenio Beltrán, Lawrence M. Day, Alice Horowitz, Thomas Marthaler, and Trevor Milner, special contributors to this book.

Salt is born of the purest of parents:
the sun and the sea.

Pythagoras, 580BC–500 BC

History and Success Stories

1. OVERVIEW

The history of salt fluoridation spans more than half a century, encompassing efforts in Europe and the Americas (see Table 1.1). The realization of how valuable salt fluoridation was in preventing dental caries resulted from a series of events dating from the middle of the 20th century. In the 1940s, Swiss physician H.J. Wespi prescribed iodized salt, which he prepared for his pregnant patients, to prevent endemic goiter and iodine deficiencies in children (*1*). Having learned of studies by H.T. Dean (*2–11*) on fluoride and caries, Wespi envisioned preventing caries on a mass scale by using fluoridated salt. Taking into account the similarities of fluoride (F) and iodine (I) as halogens, he arranged through the United Swiss Rhine Salt Works to begin adding 200 mg of sodium fluoride (NaF), which is equivalent to 90 mg of fluoride, per 1 kg of salt produced by the company, assuming an average salt intake of 10–12 g per day. In 1955, on the recommendations of Wespi and others, the United Swiss Rhine Salt Works began producing salt containing 10 mg of potassium iodide (KI) and 90 mg of fluoride (F) per 1 kg of salt, for consumption in Canton Zurich. In 1968, enriched salt was consumed in 23 of 25 Swiss cantons (*12*); currently, fluoridated salt is consumed in all 26 cantons (in 1974, a new canton, Canton Jura was incorporated, bringing the total to 26). Canton Basel City had introduced water fluoridation in 1962. In 2004, the Council resolved to switch from fluoridation of water to fluoridation of salt for various reasons, one being that the logistics of keeping fluoridated salt out of fluoridated water in Basel was becoming increasingly difficult, finally becoming legally impossible (*13*). Accordingly, fluoridated salt, available in packages up to 1 kg, is now sold all over Switzerland, and its market share among all domestic salt has been 85% since 2000.

A second important event occurred in June 1965, when distribution of fluoridated salt began in two Colombian communities in the Andes, as part of a trial to determine the effect of salt fluoridation in preventing dental caries, as compared with water fluoridation's. Sponsored by several international organizations, the United States Public Health Service, and the University of Antioquia in Colombia, this project benefited from an excellent analytical design and represents the best proof to date of salt fluoridation's effectiveness. Salt fluoridation (200 mg of fluoride per kg of salt) produced benefits similar to those of water fluoridation. Reductions in dental caries ranged from 60%–65%; such results were not observed in a control community that had neither water nor salt fluoridation.

Between 1966 and 1976, Karoly Toth conducted a trial in three Hungarian communities that consumed salt with three different fluoride concentrations—200, 250, and 350 mg of F per 1 kg of salt. Three other communities served as controls. In the communities using fluoridated salt, dental caries dropped 33% in children 2–6 years of age (primary dentition) and 66% in children 12–14 years of age (permanent dentition).

Salt fluoridation was introduced in Finland in 1952, with levels of fluoride in table salt of 90 mg per kg. Consumption of fluoridated salt increased in the 1970s, but with limited distribution. Since 1978, no fluoridated salt has been available in Finland (*14*).

In 1971 and 1985, Viñes reported the results of two studies that began in 1966 and 1968 in Pamplona, Spain (*6, 7*). The study in 1966 was restricted to a group of children 6–13 years old living in an orphanage, who received salt with a concentration of 250 mg of F per 1 kg. Given the controlled environment of the orphanage, daily consumption was en-

TABLE 1.1 Major events in the history of salt fluoridation.

Year	Country	Event
1955	Switzerland	Salt fluoridation, at 90 mg of F per 1 kg (from NaF), begun by the United Swiss Rhine Salt Works.
1964	Switzerland	Production reached 598 million tons of fluoridated salt, consumed in 20 of the total 25 cantons then in existence.
1965	Colombia	Salt fluoridation began at 200 mg of F per kg (from NaF and CaF2), as part of a trial in four. Andean communities.
1966, 1968, and 1972	Hungary	Three community trials were begun with salt at 200, 250, and, 350 mg of F per 1 kg of salt.
1966, 1968	Spain (Pamplona, Navarra and Potasas, Navarra)	Two studies of effectiveness were conducted in children 6–13 years old who consumed 250 or 225 mg of F per 1 kg of salt. Results after three years showed an approximately 50% reduction in the average number of DMFT.
1970 and 1974	Switzerland	Salt fluoridation at 250 mg F per 1 kg salt was initiated in the Canton of Vaud (1970, population 500,000) and in the Canton of Glarus (1974, population 40,000). In these two cantons, fluoridated salt has been used in households as well as institutional kitchens (restaurants, canteens, hospitals) and in bakeries.
1972	Colombia	Colombia's study of salt fluoridation ends. Data reported in 1976 indicates a 60%–65% reduction in caries, 65% in the communities that consumed fluoridated salt (caries reduction percentages were comparable to those obtained in the community that consumed fluoridated water).
1977	Colombia	First international symposium on salt fluoridation.
1982	Austria	International conference on fluorides.
1986	Guatemala	Meeting of experts on fluoridation and iodization of salt for human consumption.
1987	Costa Rica and Jamaica	Programs for fluoridation of salt at 250 mg F per 1 kg were launched.
1990–1991	Peru and Uruguay	Programs for salt fluoridation at 250 mg F per 1 kg were launched.
1991	Mexico	Meeting of experts on Salt Fluoridation in Mexico City.
1996	PAHO	Programs for salt fluoridation were launched in Bolivia, the Dominican Republic, Honduras, Nicaragua, Panama, and Venezuela in the first stage of the project financed by the Kellogg Foundation. A year later Belize and Paraguay were included.
1997	PAHO Headquarters (Washington D.C.)	Task force meets to review and issue recommendations for fluoride concentration in salt.
1998	Ecuador	First international symposium on surveillance and quality control of salt fluoridation.
2004	Cuba	Regional meeting of dental chief officers to update effectiveness of salt fluoridation.

sured at between 1.2 and 1.6 mg of F. In 1968, distribution started in the town of Potasas, Navarra, and entailed the use of salt fluoridated to 225 mg of F per 1 kg; daily consumption ranged between 0.8 and 1.2 mg of F. A comparison of decayed, missing, and filled teeth (DMFT) in children 6–13 years of age in both communities—before and three years after introducing fluoridated salt—showed reductions of around 50%. Viñes' study in Potasas, Navarra, had a control; the one in Pamplona did not (*16*).

By the beginning of the 1980s, scientific evidence clearly favored fluoridation of salt to prevent dental caries. At that time, a number of countries in the Region of the Americas launched their own national salt fluoridation programs.

The following two chapters trace the history of salt fluoridation and its later success stories.

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2. EARLY EXPERIMENTS, 1955–1980

SWITZERLAND

Salt fluoridation began in Switzerland in 1955, on the recommendation of several health care providers and authorities, with distribution of salt containing 90 mg of fluoride (F) and 10 mg of potassium iodide (KI) per 1 kg of salt. At that time, toxic levels of fluoride were unknown, and it was believed that a person should not ingest more than 2 mg a day (*1*). The United Swiss Rhine Salt Works (Vereinigte Schweizerische Rheinsalinen [VSR]) fluoridated the salt, initially using a solution containing sodium fluoride (NaF), but later replacing it with the more soluble potassium fluoride (KF). In the VSR experiments, 80%–90% of fluoride added to the salt remained present after almost four years, yet moisture increased by only 0.03% (*1*). This demonstrated that the fluoride in the salt did not deteriorate and the salt retained its physical characteristics during storage. First distributed in the city of Zurich and then in Zurich Canton, fluoridated salt was available by 1960 in 20 of the 25 Swiss cantons in existence at that time; by 1964, almost 600 metric tons were being produced.

Even though salt could be fluoridated without compromising the quality of the product, salt fluoridation's effectiveness in preventing caries remained to be proven. Such proof was difficult to come by, however, since each canton determined what method of caries prevention it would use. For example, since about 1975, most cantons gradually introduced supervised toothbrushing with a concentrated fluoride preparation of 1.25% F. Fluoride tablets were distributed in schools in a few cantons, but such measures were locally driven, and often were not followed up with sufficient consistency and the effort died out in the 1970s. By the beginning of the 1980s, they were totally abandoned (*2*). Topical fluoride programs continued after the nationwide sale of salt fluoridated with 250 ppm F had begun in 1983.

Two retrospective studies conducted between 1960 and 1962 in Zurich and Wadenswil (*3*, *4*) to measure the preventive effect of salt fluoridation (at 90 mg F/per 1 kg salt), showed lower average numbers of decayed, missing, and filled surfaces (DMFS) in children who consumed fluoridated salt than in those lacking fluoridated salt in their diets or who had consumed it sporadically. Among children 8–9 years of age, DMFS reductions of 25%–32% were recorded, while among 12–14-year-olds, evidence of such change was negligible. Overall, fluoridated salt's benefit was less than expected, maybe due to the reduced dose, the short period during which the population was evaluated (4–5 years), and a possible bias in reporting fluoridated salt consumption.

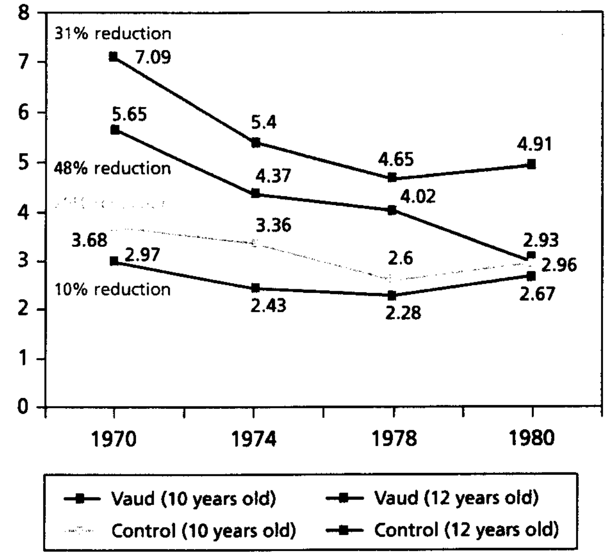
Given the limited preventive effect observed with salt fluoridation at 90 mg of F per 1 kg of salt, Canton Vaud, which had participated in the school program to distribute fluoridated supplements, in 1969 and 1970 fluoridated salt produced by the local Bex Salt Mine at 250 mg of F per 1 kg of salt. Salt used by bakeries and public dining rooms was similarly fluoridated. To avoid the increased risk of enamel fluorosis (a purely cosmetic defect in the tooth enamel caused by an excessive intake of fluorides during enamel formation), the new salt was introduced with consumer advice about not taking other fluoride supplements. No problems with enamel fluorosis were observed. In 1974, Canton Glarus (40,000 inhabitants) also began distributing salt with 250 mg of F per 1 kg.

It should be noted that fluorides have been used worldwide since then, and have proven to be indispensable for reducing and controlling caries prevalence. It has become evident that some dental fluorosis is to be expected in any effective program for controlling caries, whether it involves fluoridation of water or salt or relies solely on topical fluorides (essentially, twice daily toothbrushing with fluoride dentifrices). After some increase of fluorosis, the situation is known to become stable. An analysis of fluorosis levels in the United Kingdom covering two decades illustrates this very well (*5*).

The Vaud project conducted epidemiological surveys every four years in three of the canton's communities (Moudon, Grandson, and Vevey) and in three other communities selected as controls (Romont and Châtel-St. Aubin in the Canton Fribourg and St. Aubin in Canton Neuchâtel). Children in the Vaud communities participated in the fluoride-supplement program and consumed salt fluoridated with 250 mg of F per kg; in Grandson, children also brushed their teeth with fluoride gels (1.2% F). Children in control communities received fluoride in several vehicles: some of their families used salt fluoridated at 90 mg of F per kg until 1982; in St. Aubin and Romont some children received sporadic fluoride supplements; additionally, in St. Aubin an annual program of tooth brushing using gel with 1.2% F began in 1971 (*6*). After four years (1970–1974), the prevalence and severity of caries dropped in all communities, but to a much greater extent in those that consumed salt at 250 mg of F per kg. The rate of DMFS at age 12 decreased from 10.37 to 7.33 (29%). The reduction in decayed, missing, and filled teeth (DMFT) observed in the control communities was attributed to the use of fluoride supplements and topical fluorides. In 1980 a second evaluation reported similar results (*7*).

An evaluation of 12 years of data from the Vaud project (1970–1982) was published in 1985 (*8*). Figure 2.1 shows average DMFT values in children 10 and 12 years of age in four epidemiological evaluations over that span of time. Although the severity of caries was already low in 1970, the evaluation revealed a reduction in caries in both groups (Canton Vaud and three control communities) and in both ages: almost 50% among 12-year-olds in Vaud, compared with 31% in children of the same age in control communities.

FIGURE 2.1 Average DMFT in children 10 and 12 years old who consumed fluoridated salt (250 F/kg salt) in Canton Vaud communities and in children 10 and 12 years old in three control communities, Switzerland, 1970–1982.



Source: (8)

An interpretation of these results should take into account that caries prevalence in economically developed communities (such as in Switzerland) tends to diminish as a result of general socioeconomic development and widespread use of fluoridated toothpaste. By 1966, some 60% of dentifrices sold in Switzerland contained fluoride; by 1990, the percentage had risen to more than 90%. Given the presence of these additional factors, the effects of salt fluoridation in Vaud Canton are even more impressive. Notwithstanding, the existence of several fluoride sources in the project's experimental and control communities over varying periods of time precludes a scientifically rigorous demonstration of the absolute benefit of salt fluoridation.

HUNGARY

Starting in the mid-1960s, Hungary began three community trials with salt fluoridation (*9*):

- In February 1966, the village of Denszk, with 2,909 inhabitants, was chosen to consume salt fluoridated with 250 mg of F per 1 kg of salt; a small water processing facility began to provide the area water containing 0.1 mg of F per l.

- In May 1968, the town of Röszke, population 3,860, began receiving salt fluoridated at 200 mg of F per 1 kg.
- In September 1972, the villages of Myhalytelek and Gyalaret, with a combined population of nearly 2,900, were incorporated as a third experimental community, receiving salt fluoridated at 300 mg of F per kg (Röszke is about 10 km from Szeged and the villages of Myhalytelek and Gyalaret are between the two).

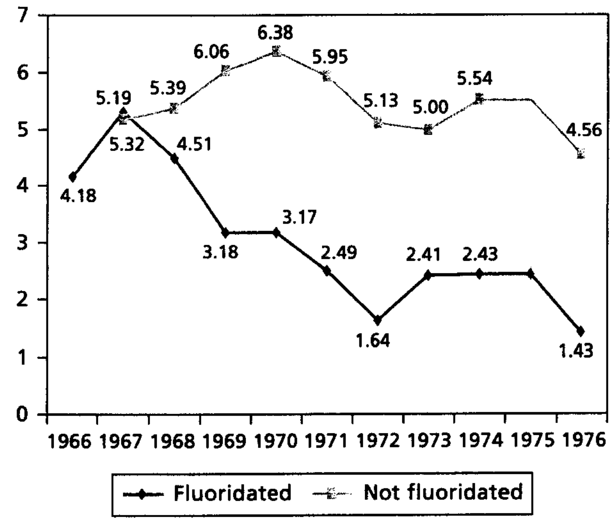
Three villages were chosen as controls: Szöreg in 1967 and Tápé and Dorozsma in 1968. Initially on the periphery of Szeged, the three control villages eventually became part of that city. The presence of primary schools in experimental and control communities meant that, other than on short trips and vacation days, most students of school age up to 14 years old remained in their communities. Each control village had a central water system that was later connected to the water of Szeged. Fluoride concentration in the water was 0.15 mg in Szöreg and 0.20 mg in Tápé, Dorozsma, and Szeged (*9*).

Each experimental village received a single type of fluoridated household salt prepared by the wet method, (see Chapter 5 for a description of dry and wet methods.) and utilizing sodium fluoride. This salt was used in food preparation in homes and community kitchens, although salt for bakeries was not fluoridated. During the study, it was prohibited to use salt from other sources or other method to prevent caries. To that end, a campaign was conducted to educate residents, schoolteachers, local authorities, and health professionals. Otherwise, the population continued its normal dietary patterns.

Clinical examinations for dental caries were conducted in each community—in schools, health centers, or cultural centers—every May, by two teams, each consisting of a dentist and an assistant using artificial light.

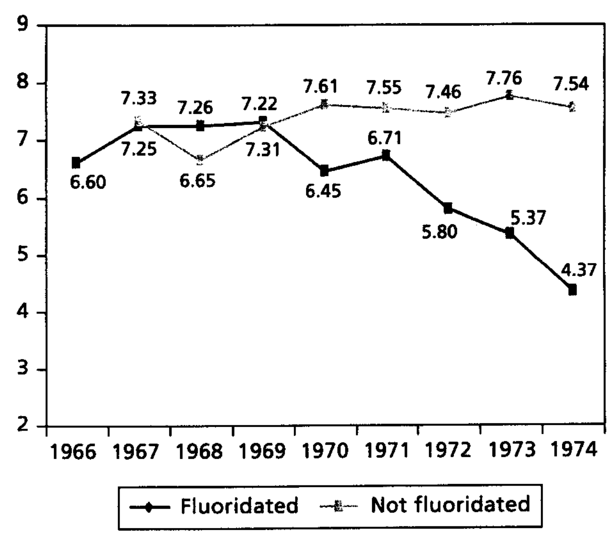
Figures 2.2 and 2.3 show trends in DMFT in children aged 2–6 and 12–14 years old, from 1966 to 1976. Information on children 7–11 years old is not presented here, but results were similar to those observed in the 12–14-year-olds. Over 10 years, the reduction in DMFT in children 2–6 years of age was 65.8% (from 4.18 to 1.43 DMFT. In children 12–14 years of age, the reduction was 59%. In control communities, indicators remained more or less stable.

FIGURE 2.2 DMFT trends in children 2–6 years old in Denszk (salt fluoridated at 250 mg of F per 1 kg salt) and in Dorozsma, Szoreg, and Tápé (controls), Hungary, 1966–1976.



Source: (9)

FIGURE 2.3 DMFT trends in children 12–14 years old in Denszk (salt fluoridated at 250 mg of F per kg salt) and in Dorozsma, Szoreg, and Tápé (controls), Hungary, 1966–1976.



The community trials in Hungary demonstrated that salt fluoridation at 250 mg of F per kg significantly reduced the prevalence of caries in successive cohorts—a result not observed in the control communities. Furthermore, comparison of results from the three experimental communities that used different fluoride concentrations indicated that as the quantity of fluoride increased so did the preventive effect.

COLOMBIA

At its first meeting in 1962, PAHO's Advisory Committee on Medical Research endorsed a proposal submitted by the Organization's Dental Health Unit that a study be conducted of the use of salt fluoridation to prevent caries. The study objectives were (*10*):

1. Investigation of the effectiveness[1] of table salt as a vehicle for fluoride in caries prevention programs
2. Comparison of the effectiveness of sodium fluoride (NaF) and calcium fluoride (CaF2) as vehicles of the fluoride ion
3. Establishment of optimal levels of fluoride in salt for its general, safe application.
4. Comparison of the effectiveness of salt fluoridation with that of water fluoridation.

PAHO's Dental Health Unit chose the Department of Antioquia in Colombia as the site of a community study and worked with a team at the Department of Preventive and Social Dentistry of the School of Dentistry of the University of Antioquia, whose members designed and implemented the study.

Four communities—Armenia, Montebello, San Pedro, and Don Matías—were selected to participate in the study because of their similar geographic, demographic, socioeconomic, nutritional, and health characteristics (*11*). A grant from the United States National Institute of Dental Research (NIDR) financed the study from 1963 to 1972.

Four interventions were implemented:

- Salt fluoridation using NaF in Armenia
- Salt fluoridation using CaF2 in Montebello
- Water fluoridation using NaF in San Pedro
- Absence of fluoridation (control) in Don Matías

The study also included a population census in each community (*12*); collection of blood samples to establish blood profile, hemoglobin, total proteins, and levels of vitamin A, carotene, and riboflavin; X-rays of the wrist to evaluate bone density and development; and a dietary survey in a random sample of 15% of the population to determine salt consumption.

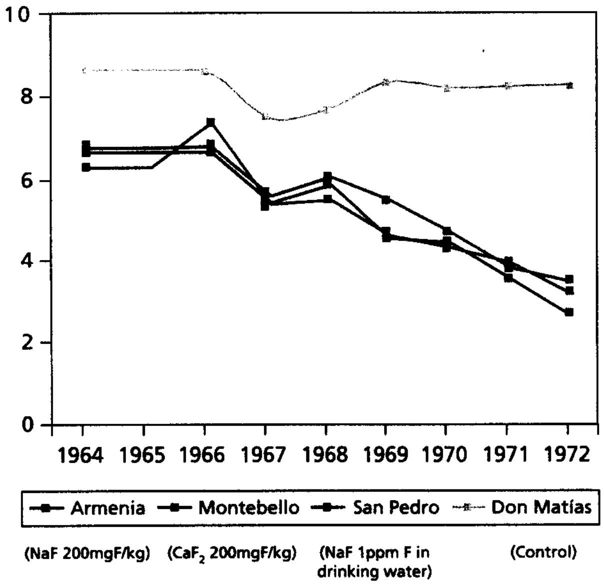
In addition, on the basis of technical recommendations and to obtain consistent, stable products, it was decided to add sodium pyrophosphate to the sodium fluoride and tricalcium phosphate to the calcium fluoride. The function of these chemicals was to buffer the salt, (neutralize any naturally occurring acid) and ensure the stability of the mixture. Furthermore, because San Pedro lacked electric power, a simple feeder line was used to supply water to that community.

Salt fluoridation began in June 1965. Fluoridated salt was prepared in the School of Dentistry of the University of Antioquia and distributed to merchants in Armenia and Montebello. Since the study absorbed the cost of distributing fluoridated salt, the new salt proved less expensive, and wholesale distributors stopped marketing salt without fluoride. In each community, a dental office was set up and a dentist named to provide emergency service—ranging from tooth extractions in the population under study to full treatment upon request for those in the population over 14 years of age, who consequently were not participating in the study (*12*).

Epidemiological assessments were conducted yearly to determine the prevalence and severity of caries in schoolchildren 6–14 years of age. Urine samples from 12–14-year-olds were analyzed as a

[1]In the original article (reference *10*) the term "effectiveness" is used. However, in the biomedical literature, the term effectiveness is restricted to the determination of the benefit in optimal controllable conditions, for example in a randomized clinical trial. We believe that the most appropriate term is "efficiency" because it denotes the benefit in common current conditions, as in the case of a preventive intervention in a whole community, where the use of the preventive element is left to the individual.

FIGURE 2.4 Average DMFT in children aged 6–14 years old, four communities, Colombia, 1964–1972.



marker for fluoride exposure and the suitability of fluoride supplementation (*12*, *13*). As shown in Figure 2.4, study results indicated that:

- The average DMFT dropped every year of the study;
- The three communities that received fluoride showed similar constant reductions in average DMFT, a significant difference from results in the community that did not receive the benefit of fluoride;
- The percentage reduction in average DMFT was higher in the youngest cohorts (who had participated in the trial from birth);
- Fluoridation from sodium fluoride and from calcium fluoride produced similar beneficial effects (however, those effects were lower, by a small percentage, than the benefit observed in the community that consumed fluoridated water).

EVIDENCE SUMMARY

The leading method for establishing the effectiveness of a preventive measure at the population level is the community trial, where one population receives the preventive measure (such as a vaccine, fluoridation, or an educational intervention) and another, similar population does not. In terms of appropriate methodologies, the experiments in Hungary and Colombia were community trials, whereas those in Switzerland were not. Except for small differences in sample size and fluoride dosage, both community trials show the effectiveness of salt fluoridation in reducing the prevalence of caries in successive cohorts. Notably, the prevalence of caries was initially higher in Colombia than in Hungary and the reduction percentages were slightly higher in Hungary—probably because a higher dosage was used.

In conclusion, adding fluoride in the form of sodium or calcium fluoride to salt for domestic consumption prevents caries, and the higher the dosage the greater the preventive effect. Salt fluoridation has been demonstrated to be an effective and practical vehicle to provide appropriate levels of fluoride to the population and, therefore, prevent dental caries.

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3. Progress and Success, 1980–2000

PAHO's Regional Oral Health Program has as its main objective the promotion of cost-effective strategies to prevent oral diseases and the adoption of targeted measures to improve equitable access to oral health services. Over the past 10 years, almost all the countries of the Americas have made significant progress in these respects.

Although the Region of the Americas continues to experience a high prevalence of dental caries, according to *Health in the Americas*, 1998 edition (*1*), it was beginning to decrease, a trend that became clearer in 2004 after analysis of additional epidemiological data from several countries. One of the most important factors contributing to that trend has been the initiation and maintenance of national programs for dental caries prevention based on the use of fluorides in accordance with technical guidelines developed by PAHO's Regional Oral Health Program (*2*). By 2001, several countries in the Americas had had salt fluoridation programs in place for at least seven years—Mexico had its program running for seven years; Uruguay for 9 years; and Costa Rica and Jamaica for 11 years. They all reported a reduction in the prevalence and severity of caries (*3–6*). Similar evaluations will be conducted in the next six years in other countries that have initiated or expanded the coverage of their salt fluoridation programs.

In 1997, PAHO's Governing Bodies approved a regional plan and strategies to set up national programs for caries prevention (*7, 8*). That plan stipulated that massive prevention programs through fluoridation of salt and drinking water be implemented, and made it possible to mobilize resources to:

1. Initiate or strengthen salt fluoridation programs in 16 countries—Belize, Bolivia, Colombia, Costa Rica, the Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, and Venezuela; and
2. Carry out water fluoridation programs in Argentina and Chile.

In most of the countries that had salt fluoridation programs, the salt industry had begun to add fluoride to salt for human consumption (*9*). In countries where salt is not produced locally, PAHO promoted the enactment of legislation mandating that only fluoridated salt be imported for domestic use. As part of these national fluoridation programs, epidemiological surveillance systems have been strengthened, improving the quality of programs as well as the collection of information by countries (*10*).

REDUCTION OF CARIES

Among the goals set forth by the Pan American Health Organization in 1999 was a 50% reduction in caries prevalence throughout the Region (*11*). To monitor progress in that effort, PAHO cooperates with countries to conduct epidemiological surveillance of caries, using cross-sectional clinical studies in specific population groups (cohorts), following protocols established by the World Health Organization (*12*).

Table 3.1 shows the prevalence and severity of caries in 12-year-old schoolchildren in several countries of the Region. It shows averages of indexes reported in epidemiological studies carried out in the 1980s and 1990s, using a wide range of sources—among them, official publications of governmental

TABLE 3.1 DMFT index and percentage reduction in children 12 years of age, selected countries of the Americas, 1980–2004.

Subregion/Country	Year (1980s)	DMFT	Year (1990–2000s)	DMFT	Reduction (%)	Annualized reduction (%)
North America						
Canada[a]	1982	3.2	1990	1.8	43.8	6.94
United States	1986–1987	1.8	1988–1991	1.4	21.8	7.86
Mexico	1988	4.42[b]	1997–1998	3.11[b, d]	29.6	3.45
	1987	4.60[c]	2001	2.0[c, d]	45.7	6.55
Central America and Panama						
Guatemala	1987	8.1	2002	5.2		
Belize	1989	6.0	1999	0.60	89.5	20.18
El Salvador	1989	5.1	2000	1.4	74.5	11.69
Honduras	1987	7.7	1997	4.0	48.4	6.41
Nicaragua	1983	6.95	1997	2.78	(1983–1997)	6.34
	1988	5.9			60.0	
Costa Rica	1988	8.4	1992	4.9	(1988–1992) 42.2	12.82
			1999	2.5	(1988–1999) 72.5	10.61
Panama	1989	4.2	1997	3.64	13.3	1.77
Andean Area						
Venezuela	1987	3.67	1997	2.1	42.2	4.13
Colombia	1977–1980	4.8	1998	2.30	52.1	3.70
Ecuador	1988	5.0[e]	1996	2.95	40.5	5.95
Peru	1988	4.8	1990	3.09[f]	N/A[g]	
Bolivia	1981	7.6	1995	4.61	39.3	3.51
Chile	1987	6.0[h]	1992	4.70	(1987–1996) 47.8	6.98
			1996	4.10[i]	(1992–1996) 12.8	3.36
			1996	3.4[d]		
Southern Cone and Northeast						
Argentina	1987	3.4				
Uruguay	1983–1987	8.5[j]	1992	4.2	(1992–1999) 40.6	7.18
		6.0[k]	1999	2.5		
Paraguay	1983	5.9	1999	3.8	35.1	2.66
Brazil	1986	6.66[l]	1996	3.1	(1986–1996) 54.0	7.47
Suriname			1992	2.7		
			2002	1.9		
Guyana	1983	2.7	1995	1.3	51.9	5.91
Caribbean						
Anguilla	1986	7.5	1991	2.5	66.7	19.73
Antigua and Barbuda	1988–1989	0.7				
Aruba			1990	2.9[m]		
Bermuda			1990	0.2		
Bahamas	1981	1.6	2000	1.3	2.5	0.14
Barbados	1983	4.4	1996	1.4[j]		
			2001	0.8		
Cuba	1984	3.9	1992	2.9		
			1998	1.6	25.6	3.64
Curaçao			2001	0.8		
Dominica	1989	2.5	1995	2.0[d]	20.0	3.65
Grenada	1984	2.6[n]	1991	5.52	(1984–1991) 1.2	10.15
			2000	2.70	(1991–2000) 50.9	7.60
Guyana	1983	2.7	1995	1.3		
Haiti	1983	3.2	2000	1.0[o]		
Cayman Islands	1989–1990	4.6	1995	1.7		
			1999	0.9	63.0	16.57
Jamaica	1984	6.7	1995	1.1	83.9	15.19

(continued on next page)

TABLE 3.1 (continued)

Subregion/Country	Year (1980s)	DMFT	Year (1990–2000s)	DMFT	Reduction (%)	Annualized reduction (%)
Dominican Republic	1986	6.0	1997	4.44	26.0	1.99
Martinique	1988	6.3				
Puerto Rico[p]			1992	3.5		
			1997	3.8		
Saint Vincent and the Grenadines			1991	3.25		
Saint Kitts and Nevis	1979–1980	5.54	1998	2.6[q]	53.4	3.84
Suriname			2002	1.9		
Saint Lucia			1997	6.0		
Trinidad and Tobago	1989	4.9	1998	5.2		
			2004	0.6		
Turks and Caicos			2002	0.9		

[a] Province of Ontario.
[b] Mexico, D.F.
[c] Mexico, State of Mexico
[d] Data sent to the Regional Oral Health Program, PAHO. Some of these studies are in press.
[e] Children 12 to 14 years of age.
[f] Population 11 years old
[g] The percentages have not been calculated because the age groups are widely different and it has not been possible to corroborate the original report(s) or the data bases.
[h] Restricted to the metropolitan region of Gran Santiago and reported in Urbina.
[i] Includes only six regions of Chile.
[j] Population of 13 to 19 years olds.
[k] Range of values in three studies reported by the Ministry of Health
[l] Urban population.
[m] Data unpublished but reported in Adewakun, 1997.
[n] Project HOPE. Results reported in Adewakun, 1997.
[o] The value corresponds to the average DMFS. Applying linear and curvilinear regression models (see Järvinen, 1983), the DMFT can be expected to be between 0.53 and 1.47.
[p] (*44*).
[q] Includes only Saint Kitts.

offices, the World Bank, WHO, and PAHO's Regional Oral Health Program (*13–43*).

The various sources of data for countries were as follows:

- Initial studies or evaluations that are part of the epidemiological surveillance system of national fluoridation programs—Belize (*45*), Bolivia (*46*), Costa Rica (*47*, *48*), Chile (*49*), the Dominican Republic (*50*), Ecuador (*51*), El Salvador (*52*), Honduras (*53*), Jamaica (*18*), Nicaragua, Panama, Paraguay (*54*), Peru (*55*), Uruguay (*29*), and Venezuela (*56*).
- A national study of urban areas conducted in 1986 and data from a comparative study conducted in 1993, Brazil (*57*).
- Studies conducted in the Province of Ontario, Canada (*20*).
- The first part of the NHANES (National Health and Nutrition Examination Survey), which gathered information between 1988 and 1991 (*21*), United States.

Table 3.1 includes the annualized percentage reduction (APR) in the prevalence of caries, following the procedures established by PAHO. (Note: The APR is positive when the final value is less than the initial value [reduction] and negative if the final value is greater than the initial value [increase].) The APR permits a more consonant comparison to be made between countries than the percentage reduction reported in *Health in the Americas*, 1998 edition, because in calculating APR, the compound rate of reduction per year in percentage is included.

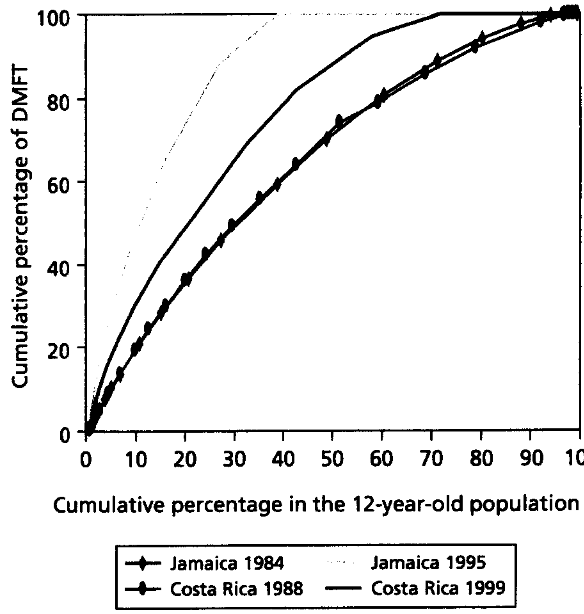
The table shows the great disparity in the average number of decayed, missing, or filled teeth at 12 years of age. In the 1980s, a DMFT of 6 was reported in Anguilla, Belize, Bolivia, Brazil, Chile, the Dominican Republic, Honduras, Martinique, Nicaragua, Jamaica, and Uruguay. In Costa Rica and Guatemala, the average DMFT was 8 or more. During the 1980s and 1990s, average DMFT values decreased from 2.5% in the Bahamas to nearly 90% in Belize. The annualized percentage reduction ranged from 0.14% in the Bahamas to approximately 20% in Belize and Anguilla. In Grenada, an increase of 112% was observed between 1984 and 1991, followed by a reduction of 51% between 1991 and 2001.

WHO established the goal of DMFT below 3 at age 12 years by the year 2000 as a benchmark for oral health under the 1979 Alma Ata Declaration on Primary Health Care (*58*). The objective of an average DMFT of 3 has been reached in Anguila, Antigua, Aruba, Bahamas, Barbados, Belize, Bermuda, Canada, Cayman Islands, Colombia, Costa Rica, Cuba, Curaçao, Dominica, Ecuador, El Salvador, Grenada, Guyana, Haiti, Jamaica, Mexico, Nicaragua, Peru, Saint Kitts, Suriname, Trinidad and Tobago, Turks and Caicos Islands, the United States, Uruguay, Venezuela, and some states of Brazil. Some countries—Bolivia, the Dominican Republic, and some regions of Chile—still present an average DMFT above 4.

Analysis of the data in Table 3.1 should take into account several factors. First, the reduction percentages and annualized reduction percentages depend on initial and final values. As a result, these figures can be imprecise due to variations in sampling, representativeness, the age groups included, and the validity and reproducibility of the information used to calculate both values. These differences tend to be more marked when the number of years between studies increases and new researchers become involved. Secondly, the reductions and analyzed figures are not absolute measures; thus, an evaluation of the percentages should take into account the initial and final values used in their calculation. For example, between 1987 and 1996, the State of Mexico reported a reduction of approximately 46% (APR = 6.6%), similar to that reported by Honduras between 1987 and 1997 (48% reduction, APR = 6.4%). Notwithstanding, in Mexico the DMFT went from 4.6 to 2.5, while in Honduras it went from 7.7 to 4.0. As the average DMFT decreases, small changes in average values, which can be the results of biases, can produce elevated percentage reductions.

These differences aside, it is remarkable that all countries exhibit reductions in the average DMFT. If the trends observed in Table 3.1 continue, most

FIGURE 3.1 Cumulative percentage of DMFT in children 12 years of age in Costa Rica (1988 and 1999) and Jamaica (1984 and 1995).



countries in the Region can be expected to bring caries under control, so they become less prevalent and less serious in their presentation, as has occurred in countries that have had preventive programs for years, such as Canada and the United States.

The cases of Costa Rica and Jamaica, as shown in Figure 3.1, illustrate the epidemiological changes that can be expected in the Region.[1] As can be observed, in the 1980s almost all 12-year-olds in both countries were affected by caries (the cumulative DMFT curve reached 100% in 100% of the population), and the disease followed the same population pattern (the curves coincide). By 1995, only 40% of 12-years-olds in Jamaica experienced caries. By 1999, 70% of 12-year-olds in Costa Rica were still affected. The difference in reductions in the two countries is due to the high prevalence and severity of dental caries in Costa Rica at the start of the national prevention program (DMFT = 8.4). If the ob-

[1]The cumulative percentages are calculated utilizing the DMFT frequency distribution: the frequencies accumulate from the end of the distribution with the highest values of DMFT until they reach a value that corresponds to the total DMFT in the population. These values are graphed according to the cumulative percentage of the population sample.

TABLE 3.2 Severity of caries and relative percentage of DMFT components in children 12 years of age, selected countries of the Americas, based on available information from the 1990s.

		DMFT severity (% of children according to DMFT level)				D, M, and F as % of DMFT in those with DMFT ≥ 0		
Country	No.	0	1≥DMFT≤3	4≥DMFT≤6	DMFT≥7	D/DMFT (%)	M/DMFT (%)	F/DMFT (%)
Belize, 1999		70.6	24.8	3.7	0.9	87.4	4.3	8.3
Bolivia, 1995	389	12.3	30.1	29.0	28.5	90.3	3.6	6.1
Costa Rica, 1999[a]	1349	28.05	39.78	26.16	6.01	33.87	4.62	61.50
Ecuador, 1996	500	22.40	41.20	26.20	10.20	84.61	6.63	8.76
United States[b]	176	50.05	32.6	16.3	1.1	27.00	1.30	71.40
Guyana, 1995	547	45.00	44.20	9.70	1.10	76.87	22.49	0.64
Honduras, 1997	307	11.7	35.8	34.2	18.2	92.1	1.8	6.1
Cayman Islands, 1995	154	39.60	44.20	11.70	4.50	50.88	0.54	48.57
Jamaica, 1995	362	59.2	29.8	10.2	0.8	72.60	9.90	17.50
Nicaragua, 1997	365	20.8	44.4	26.9	8.0	95.9	2.5	1.6
Panama, 1997	149	22.1	30.2	30.9	16.8	80.4	10.1	9.5
Paraguay, 1999	348	18.4	41.4	24.4	15.8	88.0	7.5	4.6

[a] Data reported to the Regional Oral Health Program, PAHO, in press.
[b] The percentages have been taken from the NHANES Study III, 1988–1991, and have been calculated especially for this table by Dr. E. Beltrán of the CDC.

served trend continues, the cumulative distribution in Costa Rica can be expected to approach that of Jamaica. Furthermore, countries that have launched salt fluoridation programs can be expected to experience similar epidemiological changes.

Table 3.2 presents information from a group of countries where recent epidemiological studies have been conducted. It gives the percentages of people in each of four groups categorized by the degree of severity of caries: those free from caries (DMFT = 0), those with DMFT between 1 and 3, those with DMFT between 4 and 6, and those with DMFT equal to or greater than 7. The table also presents the percentage contribution of each of the three elements of DMFT in those affected by caries (DMFT > 0). It distinguishes two groups of countries. In one group—Belize, the Cayman Islands, Guyana, Jamaica, and the United States—40% or more of 12-year-olds did not present caries (DMFT = 0). In the second group—Bolivia, the Dominican Republic, Ecuador, Honduras, Nicaragua, Panama, and Paraguay—only 10%–25% of 12-year-olds presented no caries; moreover, in Bolivia, the Dominican Republic, and Honduras, over 50% of 12-year-olds had three or more teeth affected by caries or sequelae (DMFT ≥ 3); and in Bolivia, the Dominican Republic, Ecuador, Honduras, Panama, and Paraguay more than 10% of 12-year-olds had seven or more teeth affected by caries or sequelae.

Analysis of the percentage contribution of each element of DMFT in those who experienced caries (Table 3.2) makes it possible to draw inferences about the type of oral health services the population receives. Populations with access to oral health services that offer restorative treatment have high percentages of the filled component and low percentages of the decayed and extracted components. Inversely, populations with limited access to restorative treatment present high percentages of decayed and extracted teeth. The values in Table 3.2 contrast countries such as the Cayman Islands, Costa Rica, and the United States, that have high percentages (49%–71%) of filled teeth, with countries such as Bolivia, the Dominican Republic, Ecuador, Honduras, Panama, and Paraguay, where teeth with untreated caries account for more than 80% of DMFT. The cases of Jamaica and Guyana present two situations that warrant additional interpretation. The countries present similar percentages of teeth with untreated caries (D)—73% and 77% of DMFT, respectively. Jamaica, however, has a higher percentage of people free of caries (66%) and 17.5% of DMFT represent restored teeth, whereas in Guyana only 0.6% of DMFT are restored teeth. From these data it can be inferred that Jamaica's population has, on average, greater access to restorative clinical interventions than the population in Guyana, where oral health needs are served mainly through dental extractions. This difference may result from the absence of preventive and restorative alternatives implemented at the beginning of the course of the disease; for example, Jamaica has three times as many dentists per inhabitant as Guyana. Similarly, it is possible that the low DMFT in Guyana (1.3 in 1995) results from the inclusion in this study of samples from isolated rural populations that still would not have adopted cariogenic diets (*63*). The case of Belize, which presents the lowest DMFT in the Region (0.63), likewise indicates a lack of access to restorative treatment, as reflected in a high percentage of caries that are untreated (87%).

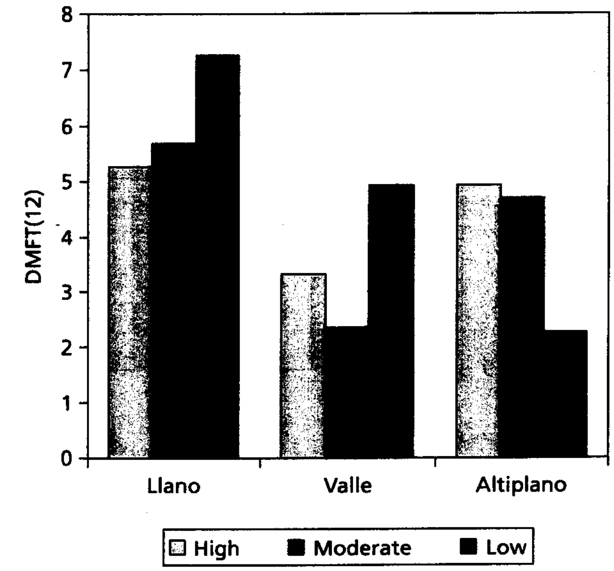
Differences among Population, Racial, and Ethnic Groups

The epidemiological change described above has not occurred uniformly over the entire population: epidemiological studies describe population groups or individuals with high prevalence and severity of disease, associated with geographic, demographic, ethnographic, and socioeconomic factors.

Differences in caries prevalence and severity among racial and ethnic groups in Guyana (1995) and the United States (1988 to 1991) were described in *Health in the Americas*, 1998 edition. Studies conducted after 1998 in the Bahamas, Costa Rica, Honduras, and Paraguay, for example, confirm those differences, namely that the groups most affected by caries are those without adequate access to preventive and curative interventions, even in countries that have national preventive programs based on salt or water fluoridation. Access to services is a direct consequence of socioeconomic level (*59*, *60*).

Despite the overall low prevalence of dental caries in countries such as El Salvador and Haiti, rural areas generally show higher prevalence than urban ones, although differences tend to be decreasing. In many Caribbean countries, for example, there is no significant difference in prevalence of dental caries between urban centers and rural communities, probably because the two are not geographically separate. In countries with diverse populations and ecosystems, however, geographic differences can be marked, especially if the socioeconomic factor is added. Figure 3.2 presents the average DMFT values for 12-year-olds in Bolivia,

FIGURE 3.2 Effect of socioeconomic level in DMFT values among children aged 12 years in three geographic regions, Bolivia, 1995 epidemiologic study.



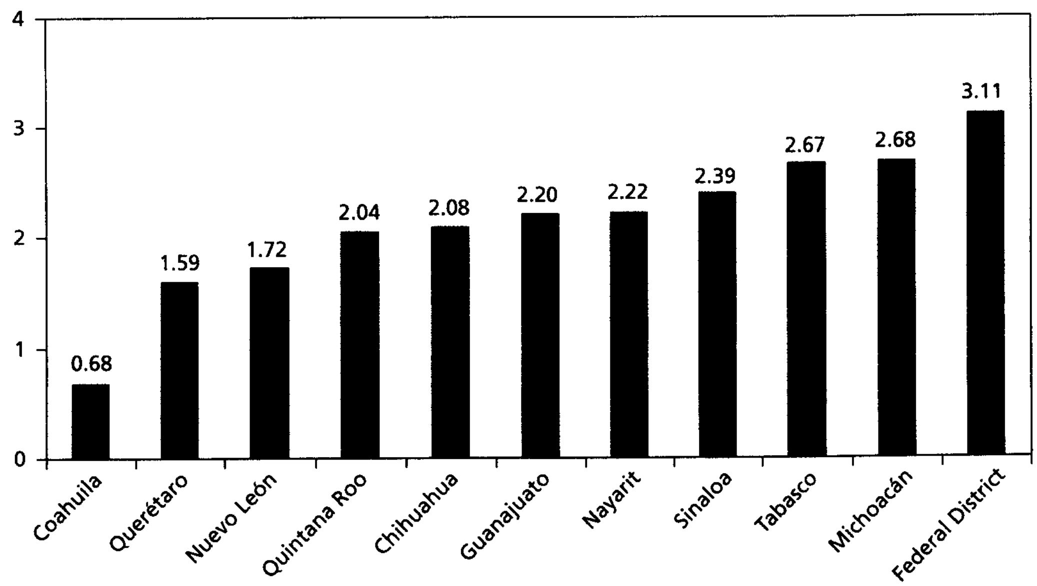
and shows how the effect of geographic factors—namely *llano* (plains), *valle* (valley), and *altiplano* (high plains)—is modified by the socioeconomic level in different areas.

Stratification of caries indexes by geographic location allows areas to be identified where the level of the disease requires specific interventions. For example, Figure 3.3 shows average values for DMFT for 12-year-olds in various states of Mexico, taken from the national epidemiological evaluation begun in 1996 (*61*); they range from 0.68 in Coahuila to 3.11 in the Federal District (the capital). Similar differences have been reported in the Bahamas (*62*) and Colombia (*31*).

MULTIYEAR PLAN TO PREVENT CARIES IN THE AMERICAS

The preventive benefits for caries of systemic fluorides in water and salt for human consumption have been demonstrated in several countries of the Americas and Europe, as shown in Chapter 2. Fluoridation of drinking water has been a significant factor in reducing the prevalence of caries in the

FIGURE 3.3 Variation in DMFT in children 12 years old, different states, Mexico.



United States and Canada (*63*). Similar benefits have been reported from consumption of fluoridated salt (*2–5, 18*).

In 1994, PAHO's Regional Oral Health Program began implementing a multiyear plan to prevent caries in the Americas, making use of salt and water fluoridation. A situational analysis of the Region's countries determined the prevalence and severity of caries (see the column corresponding to the 1980s in Table 3.1) and the existence of prevention programs. That analysis yielded a typology for classifying countries according to their oral health development (see Table 3.3). DMFT at 12 years of age (DMFT-12) is used as the principal criterion, because it is easily measured in most of the countries and allows for valid, reliable comparisons among countries. Three stages of oral health development are defined: (1) an emerging stage, with a DMFT-12 greater than 5; (2) a growth stage, with a DMFT-12 of 3 to 5; and (3) a consolidation stage, with a DMFT-12 below 3.

The plan is guided by three operating principles: caries prevention, development of technical capability, and program continuity. Under the plan, every country targets positive epidemiological change—from emerging and growth stages with high prevalence and severity of caries, to stages of consolidation with limited prevalence and severity. Toward that end, almost all countries in the Region have started water and salt fluoridation projects. Figure 3.4 shows the distribution of these programs in the Region, and Table 3.4 shows the status and coverage in each country by the end of 2001. As can be seen, not all fluoridation programs cover 100% of the population. For example:

- In Bolivia only 40% of the salt is fluoridated.
- The Dominican Republic, Guatemala, Honduras, and Nicaragua are still in initial stages of production.
- Chile has extended water fluoridation to the Santiago metropolitan area, whereas previously only the areas of Valparaiso and Viña del Mar were covered.
- Argentina now adds fluoride to drinking water in Buenos Aires; previously, only the city of Rosario had fluoridated water.

By 2010, more than 400 million people in Latin America and the Caribbean are expected to have access to fluoridated salt or water. Three countries—Costa Rica, Jamaica, and Mexico—launched salt fluoridation programs at the end of the 1980s, and their programs have been evaluated for over five years. (Other countries—among them Peru, Ecuador, and Uruguay—launched salt fluoridation programs in the mid-1990s, so medium-term epidemiological

TABLE 3.3 Oral health development typology.

A. Before 1990

Emergent DMFT > 5	Growth DMFT 3–5	Consolidation DMFT < 3
Belize	Argentina	Bahamas
Bolivia	Canada	Bermuda
Brazil	Colombia	Cuba
Chile	Ecuador	Guyana
Costa Rica	Cayman Islands	Dominica
Dominican Republic	Mexico	United States
El Salvador	Panama	
Guatemala	Peru	
Haiti	Trinidad and Tobago	
Honduras	Venezuela	
Jamaica		
Nicaragua		
Paraguay		
Uruguay		

Source: Organización Panamericana de la Salud. Estrategia Regional de Salud Bucodntal para los Años Noventa. Washington DC, mayo de 1994 (*64*).

B. Circa 1996

Emergent DMFT > 5	Growth DMFT 3–5	Consolidation DMFT < 3
Belize	Argentina	Bahamas
Dominican Republic	Brazil	Bermuda
El Salvador	Bolivia	Canada
Guatemala	Chile	Cuba
Haiti	Colombia	Guyana
Honduras	Costa Rica	Jamaica
Nicaragua	Ecuador	Dominica
Paraguay	Mexico	United States
Peru	Panama	
	Puerto Rico	
	Peru	
	Suriname	
	Trinidad and Tobago	
	Uruguay	
	Venezuela	

Source: Pan American Health Organization. XL Directing Council. Washington DC: PAHO; 1997. Document CD40/20 (*8*).

C. Circa 2004

Emergent DMFT > 5	Growth DMFT 3–5	Consolidation DMFT < 3
Guatemala	Argentina	Anguila
Saint Lucia	Bolivia	Aruba
	Chile	Bahamas
	Dominican Republic	Barbados
	Honduras	Belize
	Panama	Bermuda
	Paraguay	Brazil
		Canada
		Cayman Islands
		Colombia
		Costa Rica
		Cuba
		Curaçao
		Dominica
		Ecuador
		El Salvador
		Grenada
		Guyana
		Haiti
		Jamaica
		Mexico
		Nicaragua
		Peru
		Suriname
		Trinidad and Tobago
		Turk and Caicos
		Uruguay
		United States
		Venezuela

Source: Pan American Health Organization. Oral Health Consultation Meeting. Opportunity and Strategy for Improving General Health in the Americas through Critical Advancements in Oral Health. The Way Forward 2005–2015. Washington DC: PAHO; April 2005 (*65*).

information is not available.) The experiences in Costa Rica, Jamaica, and Mexico are analyzed in the following country sections, and the effectiveness is compared.

Costa Rica

Costa Rica launched the first salt fluoridation program in the Americas in April 1987. Until that time, only Switzerland had experimented with national coverage. Despite the success of the community trial in Colombia, the program was never expanded nationally (*75*).

Costa Rica's salt fluoridation program was initially placed under the Ministry of Health, in coordination with the Costa Rican Social Security Fund (CCSS) and the Costa Rican Institute for Research in Nutrition and Health (INCIENSA); subsequently, INCIENSA assumed complete responsibility for the project, which was financed with a subsidy from the W.K. Kellogg Foundation. Between 1992 and 1995, the program published five volumes of the journal

FIGURE 3.4 Status of salt fluoridation programs, Region of the Americas, 2004.

Source: PAHO

Fluoridation Update, reporting on several aspects of the program, especially studies related to chemical and biological monitoring. Highlights of the program follow.

Salt consumption was estimated at 10 g per person per day. Salt in Costa Rica is fluoridated using the dry method and NaF. The initial concentration was 250 ± 25 mg of F per 1 kg, but in 1994 the dose was reduced to 150–200 mg of F per 1 kg, after enamel fluorosis was reported in some cohorts of children who had consumed salt during tooth formation. Retrospectively, however, the levels of fluorosis were reported to be very low. Following an international meeting of experts in 1999, the fluoride concentration adopted by Costa Rica was 200 ± 25 mg of F per 1 kg salt.

Salt was locally produced by seven plants throughout the country. Quality control was carried out by the salt plants locally and centrally at INCIENSA, with periodic data recording and monthly evaluations. INCIENSA obtained salt samples from supply centers and analyzed 15–20 samples from each plant. Salt distribution is strictly controlled in Costa Rica, since in some areas there is a high level of natural fluoride in drinking water, and thus only nonfluoridated salt should be sold there. Quality control shows that Costa Rican salt is consumed within four months of being produced.

The initial dosage (250 mg of F per 1 kg salt) was established after review of dosages used in Switzerland (90 and later 250 mg of F per 1 kg salt), Hungary (250 mg of F per 1 kg salt), and Colombia (200

TABLE 3.4 Countries with programs for water or salt fluoridation in the Region of the Americas at the end of 2001.

Country	System	Coverage	Status
Argentina	Water	Data is not available	Operational
Belize	Salt	National	Initiated
Bolivia	Salt	40% coverage	Operational
Brazil	Water	60% of the population with drinking water systems	Operational
Canada	Water		Operational
Chile	Water	National	Operational
Colombia	Salt	Incomplete data	Operational
Costa Rica	Salt	National	Operational
Cuba	Salt	National	Operational
Dominican Republic	Salt	National	Operational
Ecuador	Salt	National	Operational
El Salvador	Salt	National	Initiated
Grenada	Salt		Planned
Guatemala	Salt	Data not available	Initiated
Guyana	Salt	National	Importation of fluoridated salt planned
Honduras	Salt	National	Initiated
Jamaica	Salt	National	Operational
Mexico	Salt	National	Operational
Nicaragua	Salt	National	Initiated
Panama	Water	National	Initiated
Paraguay	Salt	National	Initiated
Peru	Salt	Incomplete data	Operational
Suriname	Salt	National	Importation of fluoridated salt planned
United States	Water	Approximately 67% of the population with drinking water systems	Operational
Uruguay	Salt	National	Operational
Venezuela	Salt	National, at less than 100 mg of F per kg	Operational

mg of F per 1 kg salt), and after analysis of the results of studies of fluoride concentration in urine and water.

Urine studies were conducted using different methodologies: 24-hour samples, specific samples (for example, at 9 a.m. and two hours after lunch), individual samples (from the person), and collective samples (from the school). The studies were conducted in groups of children 7–13 years of age in schools and in young adults 20–30 years of age in soccer stadiums. Results were similar for both groups, with fluoride concentration in urine ranging between 0.24 and 0.44 mg of F among 7–13 year olds and between 0.30 and 0.42 mg of F in adults. In June and October 1987 and again in 1988, studies were conducted of fluoride in urine in 16–22-year-olds. Despite the limited number of samples, an increase in fluoride in urine, associated with consumption of fluoridated salt, was detected. For example, in Cantón Siquierres (Limón) samples collected at 9 a.m. and 1 p.m. had average concentrations of 0.75 and 0.80 mg of F, respectively, an increase over the 0.44 mg of F obtained in June 1987, a few months after fluoridation began. Later, stabilization of fluoride concentrations in urine—ranging between 1.0 and 1.7 mg of F—was observed.

The water study revealed areas with naturally occurring fluoride (*67*). The most significant of these is in the Cantón Central in the Province of Cartago and neighboring sectors of cantons Oreamuno and Alvarado. In the communities of Tierra Blanca and Llano Grande, natural fluoride concentrations in water range between 0.8 mg FAI (Free Androgen Index) in the rainy season and 1.4 mg FAI in the dry season. Those communities, moreover, are in an area characterized by the presence of volcanic eruptions. Studies in 1986 and 1988 of fluoride in urine and fluorosis in children 5 and 7 years old in Tierra Blanca and Llano Grande found that fluoride concentration in urine ranged between 0.47 and 3.3 mg of F per liter and that the prevalence of very mild to more intense fluorosis was 47%. Both values are above what would be expected in a community with a maximum level of 1.4 mg of F in the drinking water. In 10 children with moderate to serious fluorosis, a fluoride concentration in urine higher than 1.5 mg of F was observed.

Salt marketed in Tierra Blanca and Llano Grande does not contain fluoride. Taking into account the levels of fluorosis observed and the concentration of fluoride in the water, it is probable that children in these communities receive additional fluoride from various sources, such as volcanic gases boiled from drinking water to prepare food or feeding bottles. INCIENSA researchers plan to conduct a more specific study in Tierra Blanca and Llano Grande to determine the different fluoride sources. It is important to note that Costa Rica's salt fluoridation program includes an educational campaign in communities with natural fluoride, promoting awareness of the availability of non-fluoridated salt (*67*).

Since 1984, when a national study of oral health was conducted, epidemiological studies have been carried out every four years on 12-year-old schoolchildren. In 1988, a year after the fluoridation program was launched, a second national study was conducted (*16*). Between 1984 and 1988, the epidemiology of caries in Costa Rica had changed very little. Average DMFT in children 12 years old was 9.1 in 1984 and 8.4 in 1988, a reduction of 0.7 possibly explained by intrinsic differences in the design of the two studies. In 1992, a national study of 12-year-old schoolchildren yielded an average DMFT of 4.9, a reduction of 40% compared to the average DMFT in 1988 (*68*). In 1996, as part of the national nutrition study, data on the state of dentition of children 7–12 years old indicated that the average DMFT for 12 year olds was 4.9, which is comparable to the value obtained in 1992 (*47*). Finally, preliminary data from the latest epidemiological evaluation of caries and the first national evaluation of enamel fluorosis carried out in 1999 showed an average DMFT of 2.5 at 12 years of age, confirming the downward trend of the prevalence and severity of caries in Costa Rica (*69*).

An important aspect of Costa Rica's program for salt fluoridation was the designation of a sentinel site to monitor caries and enamel fluorosis. The Cantón La Unión-Cartago was chosen for that purpose, to represent socioeconomic and population characteristics similar to those of the average Costa Rican canton. Between 1990 and 1993, four epidemiological studies of samples of children 7 and 12 years old were conducted at the sentinel site.

Finally, data from the latest epidemiological evaluation of caries and the first national evaluation of enamel fluorosis carried out in 1999 showed an overall mean DMFT of 2.46 at age 12 and of 4.37 at age 15. Regional differences were observed, with the DMFT at age 12 ranging from 1.93 to 3.86. Compared with pre-fluoridation data collected in 1984, schoolchildren aged 12 years experienced a 28% decrease in prevalence (from 100% down to 72%) and a 73% decrease in severity (DMFT from 9.13 to 2.46, representing an 8.3% compound annual percent reduction).

Prevalence of very mild or greater enamel fluorosis at age 12 years was 17% for teeth 13 to 23 and 32% when teeth 14 and 24 were included. At age 15 years, the prevalence was 12% for teeth 13 to 23 and 25% when teeth 14 and 24 were included. Large regional differences were observed, ranging from 10% to 76% among 12-year-olds and from 6% to 50% among 15-year-olds. The prevalence of enamel fluorosis is within the range expected for a salt fluoridation program, but regions with higher severity should investigate further on additional sources of fluoride, including environmental ones.

Between 1984 and 1999, Costa Rican schoolchildren experienced substantial reductions in caries prevalence and severity. Many factors may be involved in this decline, but the most likely appears to be exposure to fluoridated salt.

Jamaica

Although Costa Rica was the first country to initiate salt fluoridation in the Americas, Jamaica was the first country that launched a nationwide program. Between 1985 and 1986, Jamaica's Parliament and the Ministry of Health established final legal arrangements for launching the program. In 1987, a proposal for a national salt fluoridation program was introduced, feasibility studies undertaken, personnel at Alkali Ltd., the salt production facility, trained (*70*), a dietary survey carried out (yielding average consumption of 7.8 g of salt per person per day), and a caries survey conducted (*71*). In September of that same year, five months after Costa Rica had launched its program, Jamaica undertook a wide ranging campaign to promote the use of salt fluoridation to prevent dental caries, which was followed by the production and sale of fluoridated salt to 2.4 million of its inhabitants (*70*).

During the 1970s and 1980s, Jamaica undertook several preventive interventions against caries, including the use of fluoride rinses and fluoride supplements among schoolchildren. In addition, during the 1970s it was proposed to fluoridate the water in Kingston, the capital. Unfortunately, most of these programs were of limited duration and were terminated for lack of financial support.

The most important factors in Jamaica's decision to fluoridate salt for household use instead of relying on fluoridated water, was the absence of water distribution networks, the use of rainwater in rural areas, and the presence of a single salt producer for the country. That producer buys salt from the Bahamas and processes it for domestic consumption and for export to other areas of the Caribbean (*70*). Only salt for domestic consumption is fluoridated, by spraying it with a potassium fluoride solution.

Jamaica's Ministry of Health monitors the program. To that end, it carried out urine studies in four groups (age groups 2–6, 7–11, 12–17, and 18–70 years old) prior to launching the fluoridation program and 20 months after. Urine samples were collected in two or three time periods with extrapolation to 24 hours (*72*). Fluoride excretion was expressed as rate of urinary excretion, using µg/24 hours, instead of µg/h, as the unit of measure to compensate for the lack of uniformity in intake of fluoridated salt during the day (*73*). Values before salt fluoridation ranged between 169 and 485 µg/24 hours; 20 months later they had increased to 304 to 657 µg/24 hours. In children from 2 to 6 years old, the high-risk age for enamel fluorosis, the values increased from 14.3 µg/h to 30.3 µg/h in those that drank water with a fluoride concentration under 0.25 mg/l, and they increased from 20.2 µg/h to 29.4 µg/h among children whose drinking water contained between 0.31 and 0.50 mg/l. These values are equivalent to those obtained in Swiss children who consume water fluoridated at optimal levels (*73*).

As a part of the evaluation of the program's effectiveness, an epidemiological oral health survey was carried out in 1995, comparing values obtained at that time with those from a 1984 survey (prior to implementation of the program). Age specific DMFT means observed in 1995 were 0.2 at age 7, 0.4 at age 8, 1.1 at age 12, and 3.0 at age 15. Mean DMFT scores in children 6, 12, and 15 years of age were dramatically lower than the corresponding scores of 1.7, 6.7, and 9.6 obtained at the baseline examination in 1984 for children of the same age groups (baseline data for 7- and 8-year-olds were not collected). The mean percentage of sound permanent teeth for all age groups was 90% in 1995. The 1995 oral health survey indicated a significant decline in dental caries compared with findings in 1984. The major change in Jamaica during those years was the introduction of salt fluoridation in 1987 (*18*).

Mexico

At the end of 1988 and beginning of 1989, the State of Mexico, one of 32 Mexican states, launched a program to fluoridate salt at a concentration of 250 mg of F per 1 kg. Carried out in coordination with Sales del Istmo, a company that controls 90% of the salt market in the State of Mexico, the program had achieved broad coverage by 1992. In 1995, more than half of salt sold had fluoride concentrations between 200 and 300 mg of F per kg. In 1993 and 1994, most salt sold in the state had concentrations between 100 and 199 mg of F per kg.

A study of salt consumption carried out in 1986 among 430 families from four localities in the state (*74*) showed that consumption increased with age. In children 1–3 years old, average consumption was 1.9 g/day; in those 4–6 years of age, it was 3.4 g/day; and in adults 23–50 years old, it was 6.9 g/day for men and 5.4 g/day for pregnant women. From those average values, investigators estimated that the daily fluoride intakes with salt fluoridated at 250 mg of F, would be 0.5, 0.8, and 1.3 mg per day in these three age groups. Note that there are two areas in the State of Mexico—Zumpango and Tenango del Valle—where the concentration of natural fluoride ranges from 0.7 to 1.5 mg per 1 l.

Two epidemiological surveys of school-age populations 5–12 years old were conducted in 1987 and in 1996. Findings from those surveys are analyzed, along with data from the Costa Rican and Jamaican experiences, in the following section.

In 1991, Mexican national health authorities established a national caries prevention program based on consumption of salt fluoridated at 250 mg per kg. Fluoridated salt was introduced gradually, reaching a total of 279,700 tons per year in 1999. Mexico has geographic areas with optimal concentrations of fluoride in the drinking water; consequently, as in Costa Rica, it was important to monitor the use of systemic fluoride compounds, design and distribute maps of areas with natural fluoride in water, and distribute non-fluoridated salt in areas with natural fluoride. That monitoring indicated that no community with concentrations of natural fluoride of at least 0.7 mg per liter should receive fluoridated salt.

In addition, 58 million schoolchildren in Mexico received a broad range of caries prevention interventions—from instruction on oral hygiene to fluoride rinses, topical applications of fluoride, and sealants. Regulations prohibited the prescription and sale of fluoride supplements to those children.

From 1987 to 1989, an epidemiological survey was carried out involving representative samples from ten states (Baja California Sur, Colima, Chiapas, Guerrero, Morelos, Hidalgo, Tabasco, Nuevo León, Yucatán, and the State of Mexico) and the Federal District. In 1996, a second national survey of caries and enamel fluorosis included samples from children 6–10, 12, and 15 years of age from each state (*61*). Evaluation of epidemiological changes in the states based on those two studies is still pending.

Effectiveness of the Programs in Costa Rica, Jamaica, and Mexico

Salt fluoridation programs in Costa Rica, Jamaica, and Mexico incorporated, within their plans for epidemiological assessment, frequent monitoring of the prevalence and severity of caries and fluorosis in indexed age groups, as has been indicated. The frequency of these studies varied according to the availability of resources. Because of the programs' nationwide coverage (Costa Rica and Jamaica) or statewide coverage (in the State of Mexico), annual surveys could not be conducted, as they had been in community trials in Hungary and Colombia, nor were control groups available. As a result, the programs should be evaluated by comparing before-and-after data, taking into account that any reduction should be interpreted within the frame of reference of trends in the epidemiology of the disease, which can be an increase in disease prevalence or a decrease in disease prevalence. It should be recalled that, due to the magnitude of its program, Costa Rica set up a sentinel site.

Epidemiological data on the average number of decayed, missing, and filled teeth (DMFT) in the primary dentition in children 6–8 years of age in Jamaica, the State of Mexico (Mexico), and Costa Rica are shown in Table 3.5 and Figure 3.5, including four studies of children 7 years of age from Costa Rica's sentinel community. Table 3.5 shows that between 1996 and 1999 the severity of caries in Costa Rica dropped 35% (from 4.3 to 2.8), for an annualized reduction of 13.4%. In the State of Mexico, the reduction between 1987 and 1996 was 28%, for an annualized reduction of 3.6%. Unfortunately, no data for primary dentition in 1984 are available, making it impossible to calculate the reduction percentages. In comparing these values, it should be taken into account that, although the program in the State of Mexico began in 1988 and 1989, effects were poor until 1995, possibly explaining the limited initial response to the program. In addition, the Costa Rican children exhibited a high degree of reduction in a short period of time, but indirect information from the sentinel group indicates that the prevalence was quite high at the beginning.

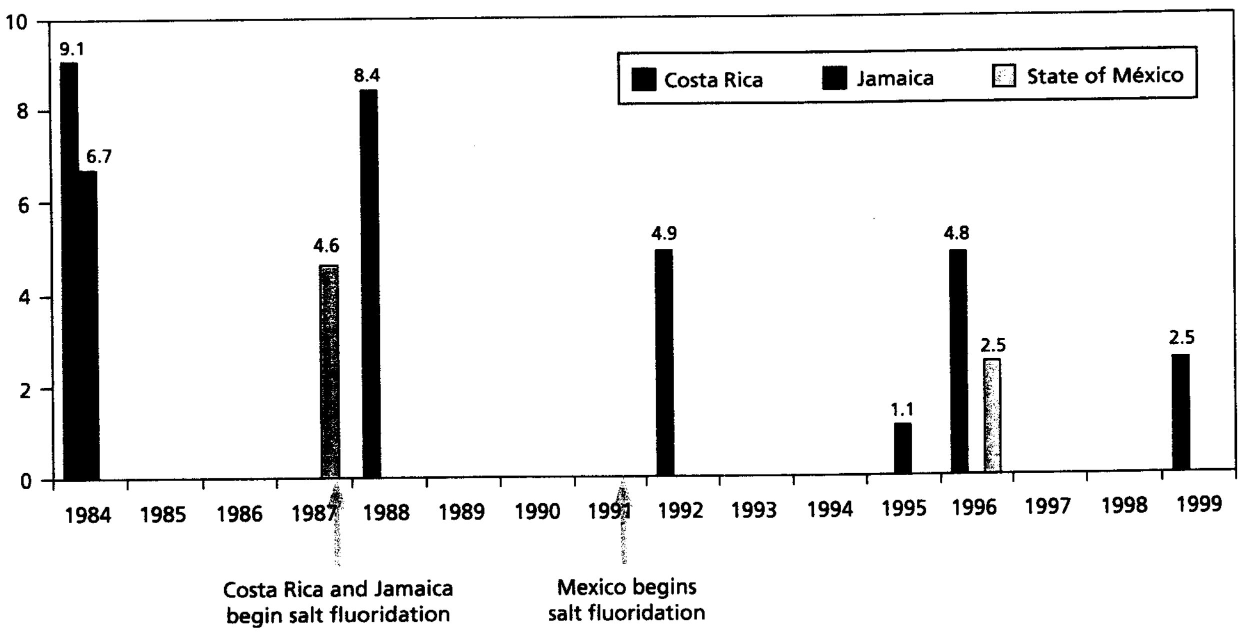
Table 3.6 shows the average DMFT values in the three countries evaluated (Costa Rica, Jamaica, and Mexico). In Costa Rica, the reduction between 1988 and 1992 was 42% (12.6% annualized); between 1988 and 1999 it was 70% (10.4% annualized). These percentages are very significant, given the high prevalence of dental caries at the program's beginning. (Note that the reduction percentages for

TABLE 3.5 Average number of decayed, missing, and filled teeth (DMFT) in the primary dentition of children 6–8 years old, Costa Rica, Jamaica, and the State of Mexico (Mexico).

	Baseline		Follow-up 1		Follow-up 2		Baseline at 1		Follow-up at 1–2	
							PR[a]	APR[b]	PR[a]	APR[b]
Country/State	Year	μ	Year	μ	Year	μ	(%)	(%)	(%)	(%)
Costa Rica	1990	5.7	1996	4.3	1999	2.8	–	–	35	13.4
	1991	5.6	–	–	–	–	–	–	–	–
	1992	4.8	–	–	–	–	–	–	–	–
	1993	4.3	–	–	–	–	–	–	–	–
Jamaica	n/a	n/a	1995	1.9	–	–	–	–	–	–
State of Mexico (Mexico)	1987	6.5	1996	4.7	–	–	28	3.6	–	–

[a] PR, percentage reduction
[b] APR, annual percentage reduction
– no data

FIGURE 3.5 Trend in DMFT at 12 years of age, Costa Rica, Jamaica, and State of México (Mexico), 1984–1999.



Costa Rica are not calculated utilizing 1984 values, because salt fluoridation did not start until 1987.)

In Jamaica, the reduction between 1984 and 1995 was 84%, an annualized average of 15.2%. However, since salt fluoridation began in 1987 and the available data are from 1984, actual percentages were probably somewhat lower than the ones observed. Presuming that the prevalence of caries in 1987 was equal to that observed in 1984, which overestimates the annualized percentage because secular changes are ignored, the reduction declines to 10%, similar to that observed in Costa Rica.

In the State of Mexico, the reduction between 1987 and 1996 was 46%, for an annualized average of 6.6%, indicating lower percentages than those observed in Costa Rica and Jamaica. These averages, however, are highly suggestive of the effect of salt fluoridation in preventing caries in permanent dentition since, as indicated previously, an optimal result was not available until 1995.

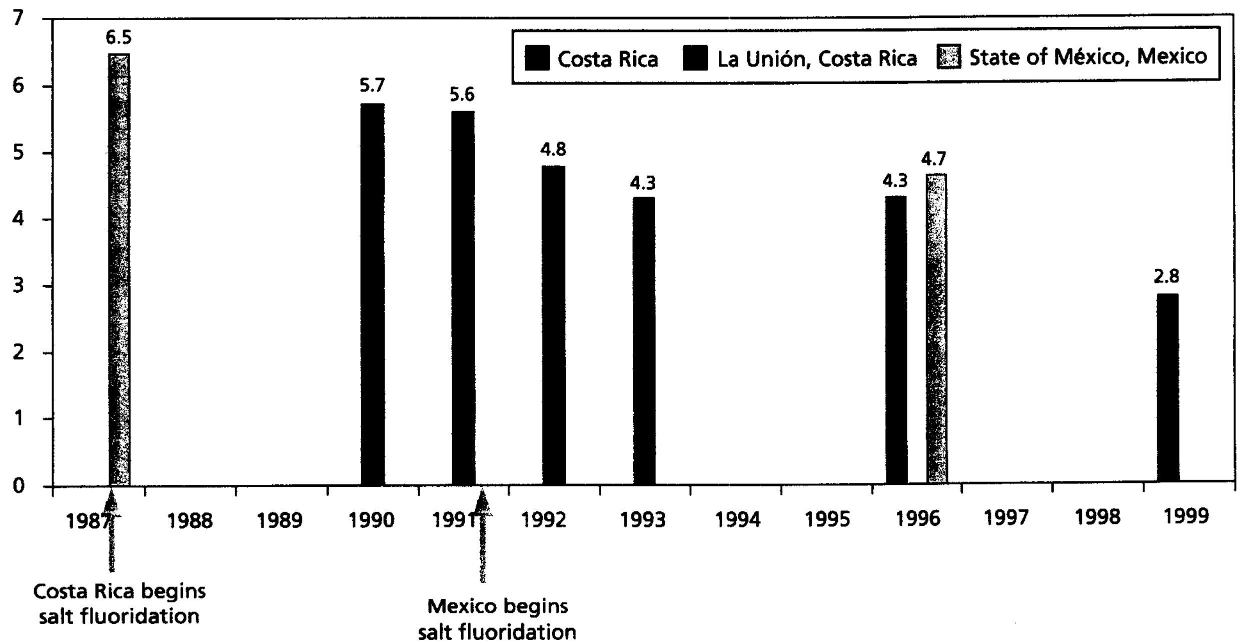
Figure 3.6 shows the results of the different studies in the three countries. Note the gradual reduction in the severity of caries in Costa Rica, where there are more points for comparison. Furthermore, Figure

TABLE 3.6 Average number of decayed, missing, and filled teeth (DMFT) in the permanent dentition of children 12 years old, Costa Rica and Jamaica, and State of México (Mexico).

	Baseline		Follow-up 1		Follow-up 2		Baseline at 1		Follow-up at 2	
Country	Year	Average	Year	Average	Year	Average	Year	APR* %	PR** %	APR* %
Costa Rica	1984	9.1	1992	4.9	1999	2.5	1992[a]	12.6	70[b]	10.4
	1988	8.4	1996	4.8						
Jamaica	1984	6.7	1995	1.1			1984	15.2		
State of Mexico (Mexico)	1987	4.6	1996	2.5			1996	6.6		

[a] 1988–1992
[b] 1988–1999
* APR, annual percentage reduction
** PR, percentage reduction

FIGURE 3.6 Trends in average DMFT in children 6–8 years in Costa Rica and the State of México (Mexico), and in children aged 7 years in La Unión, Costa Rica (sentinel site), 1987–1999.

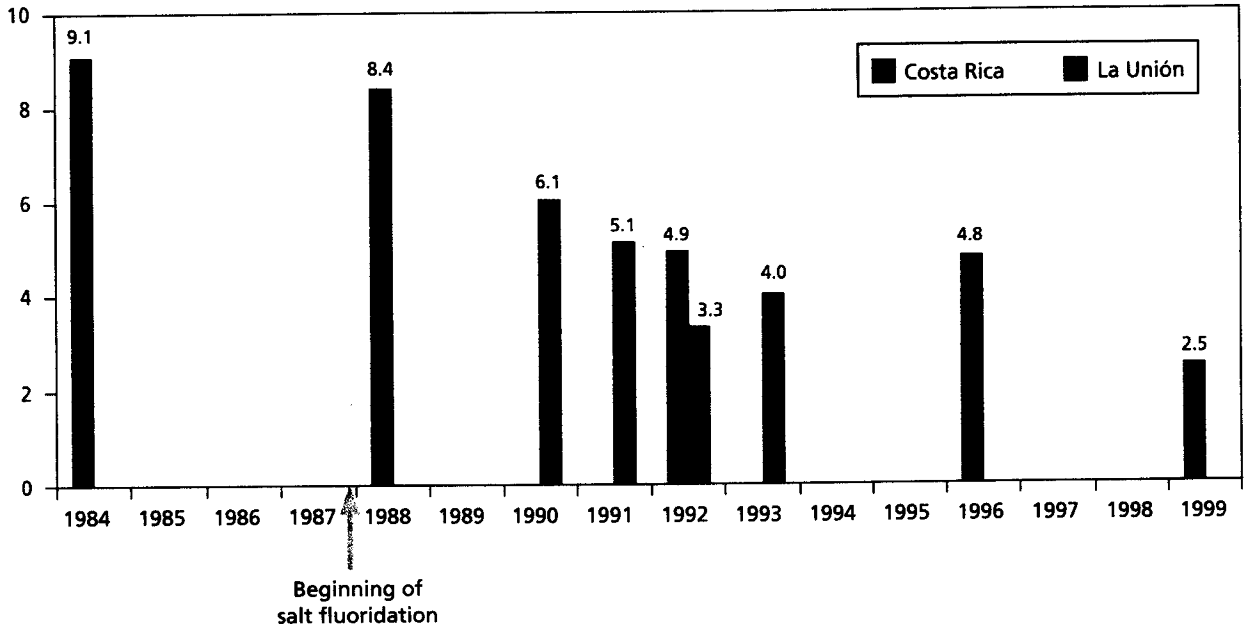


3.7 includes data obtained at the sentinel site, to demonstrate that the use of sentinel sites is useful for monitoring preventive programs. In interpreting the discrepancies observed between 1992 and 1996, a possible bias in selection at the beginning and the end of that period should be considered in La Unión, where only 60 children 12 years of age were examined, because in the overall study, the group sampled contained children from 7 to 12 years of age.

In comparing the effectiveness of salt fluoridation in preventing caries in the three countries, it should be noted that the prevalence and severity of caries in the initial studies were lower in the State of Mexico and higher in Costa Rica. That means that if trends toward reduction of prevalence and severity observed in Costa Rica continue, the same average values observed in Jamaica should be reached in Costa Rica.

In short, the experiences in Costa Rica and Jamaica show the benefit of salt fluoridation in preventing caries. In the State of Mexico, additional evaluations are needed to estimate the correct reduction, because there were problems in producing the fluoridated compound.

FIGURE 3.7 Trend in DMFT of children 12 years old, Costa Rica, national data and data from La Unión, Costa Rica (sentinel site), 1984–1999.



ENAMEL FLUOROSIS

Enamel fluorosis is not a disease, as is caries. Rather, it is a disturbance in the mineralization of the dental enamel resulting from exposure to high fluoride levels in the late formative and maturational stages of tooth development. For most teeth, that development occurs during the first six years of life, or the first eight years if one includes the second premolars and the second permanent molars. For the central incisors, the critical period is the first 18 months of life (*75*).

In every preventive program that administers systemic fluoride to children under 8 years old, an increase in the prevalence and severity of enamel fluorosis should be expected. If the program restricts consumption of fluoride in salt and water to within levels recommended for the first 6 years of life (see the chapter on "Epidemiological Surveillance"), a prevalence of the mildest forms of fluorosis (10%–15%) is to be expected. For that reason, enamel fluorosis is one of the conditions recommended for inclusion in epidemiological surveillance programs in the Region. It is important to note that the role of fluoride supplements (pills, tablets, lozenges, drops) in public health has been limited (*76*).

Table 3.7 presents information on the prevalence and severity of enamel fluorosis for selected countries for which information is available. Prevalence ranges from 2% in Honduras to 26% in Valparaiso and Viña del Mar in Chile. Fluoride sources ingested during the first six years of life should be taken into account in evaluating data in the table. For example, in the United States and Chile (specifically, Valparaiso), high prevalence is possibly due not only to consumption of water fluoridated at optimal levels, but also to ingestion of fluoridated toothpaste. The effect of other fluoride sources on fluorosis prevalence can be inferred from the 9% prevalence reported in Santiago, where drinking water contained only negligible quantities of fluoride at the time data in the table were reported. The high prevalence (24%) in the Bahamas, could be explained by the existence of widespread prevention programs using fluoridated supplements; those programs have ended, and the prevalence of enamel fluorosis can be expected to decline in successive cohorts. An analysis of the prevalence and severity of enamel fluorosis in countries that launched salt fluoridation programs with financial support from the W. K. Kellogg Foundation has been presented and analyzed in PAHO's final report to the foundation (*77*).

TABLE 3.7 Distribution of the level of severity of enamel fluorosis among children 12 years of age, applying Dean's fluorosis index.

<table>
<tr><th>Country</th><th>No.</th><th>None (%)</th><th>Questionable (%)</th><th>Very low (%)</th><th>Low (%)</th><th>Moderate (%)</th><th>Serious (%)</th><th>Prevalence (very low or greater) (%)</th></tr>
<tr><td>Bahamas, 1999–2000</td><td>854</td><td>59.1</td><td>16.6</td><td>14.5</td><td>7.4</td><td>1.7</td><td>0.7</td><td>24.3</td></tr>
<tr><td>Belize, 1999</td><td>323</td><td>66.3</td><td>10.8</td><td>14.8</td><td>5.3</td><td>1.2</td><td>1.5</td><td>22.8</td></tr>
<tr><td>Bolivia, 1995</td><td>287</td><td>58.5</td><td>23.7</td><td>15.7</td><td>1.7</td><td>0</td><td>0</td><td>17.4</td></tr>
<tr><td>Chile, 1994</td><td>125[a]</td><td>44.0</td><td>30.4</td><td>21.6</td><td>2.4</td><td colspan="2">1.6</td><td>25.6</td></tr>
<tr><td></td><td>203[b]</td><td>80.8</td><td>9.3</td><td>7.3</td><td>1.5</td><td colspan="2">0.5</td><td>9.3</td></tr>
<tr><td>Colombia, 1998</td><td>PS[c]</td><td>66.8</td><td>14.5</td><td colspan="2">17.5</td><td colspan="2">1.1</td><td>18.7</td></tr>
<tr><td>Costa Rica, 1999</td><td>PS[c]</td><td>74.1</td><td>9.1</td><td>10.6</td><td>3.8</td><td>2.0</td><td>0.4</td><td>16.8</td></tr>
<tr><td>Ecuador, 1996</td><td>500</td><td>90.0</td><td>5.2</td><td>1.6</td><td>2.4</td><td>0.8</td><td>0</td><td>4.8</td></tr>
<tr><td>El Salvador, 2000</td><td>524</td><td>93.1</td><td>2.86</td><td colspan="2">1.84</td><td colspan="2">2.24</td><td>4.1</td></tr>
<tr><td>USA, 1987[d]</td><td>PS[c]</td><td>42.6</td><td>36.0</td><td>16.2</td><td>4.4</td><td>0.4</td><td>0.4</td><td>21.4</td></tr>
<tr><td>Honduras, 1997</td><td>307</td><td>92.1</td><td>5.6</td><td>1.3</td><td>0.0</td><td>0.7</td><td>0.3</td><td>2.3</td></tr>
<tr><td>Nicaragua, 1997</td><td>365</td><td>82.7</td><td>9.9</td><td>4.9</td><td>1.9</td><td>0.6</td><td>0.0</td><td>7.4</td></tr>
</table>

[a] Children 7 and 12 years of age in Valparaiso and Viña del Mar, with 1.0 ppm of F in the drinking water.
[b] Children 7 and 12 years of age, in Santiago, with negligible concentration of F in drinking water.
[c] Probalistic sampling.
[d] Results obtained from a subsample of 12-year-old children that had lived in a single place throughout their lives, whose drinking water had been adjusted to optimal fluoride levels (0.7–1.2 mg/l) and who were not reported to have consumed fluoride supplements in infancy [Beltrán and others. JADA 2001].

The high prevalence observed in Belize, Bolivia, Costa Rica, the Dominican Republic, and Paraguay can be explained by the existence of communities that consume water containing natural fluoride. Costa Rica's, national salt fluoridation program permits the marketing of fluoridated salt only in communities where the fluoride concentration in water is less than 0.3 mg/l (*67*). However, a recent study in Costa Rica (*78*), identified additional communities (not identified in the initial study in 1988) with naturally occurring fluoride. It is to be expected that the prevalence and severity of fluorosis in these communities are elevated. Costa Rican health authorities are evaluating the possibility of reducing natural fluoride concentrations or including these communities in areas where no fluoridated salt should be sold.

Belize has areas with fluoride concentrations above 1.5 mg/l, where fluoridated salt from Mexico and Jamaica is consumed; the combined consumption of fluoride from both sources is sufficient to produce the higher levels of enamel fluorosis observed. The 7% of fluorosis observed in Nicaragua prior to implementation of the salt fluoridation program can be explained by the existence of natural fluoride in Managua's drinking water (around 0.6 mg/l). Low concentrations of fluoride in Ecuador, El Salvador, Honduras, and Nicaragua in cohorts not exposed to fluoridated salt from birth, can be expected to increase as successive cohorts reach the age of examination (12 and 15 years).

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Where would we be without salt?

James Beard, Master Chef

Planning, Launching, and Running a Salt Fluoridation Program

4. EDUCATING COMMUNITIES ABOUT SALT FLUORIDATION[1]

Appropriate use of fluoride is the foundation of any strategy to prevent tooth decay, also known as dental caries. Salt fluoridation is a safe and effective method of preventing this disease. Just as fluoride is essential to prevent dental caries, education about use of fluorides is essential to ensure acceptance and continuation of a program of salt fluoridation.

Educating the public, policymakers, health care providers, the mass media, and salt manufacturers is critical to successfully implement and maintain salt fluoridation. All too often, educating these groups is given little or no attention. This chapter describes opportunities and responsibilities for providing education about salt fluoridation and discusses the roles of various groups in such an effort.

The consequences of providing inadequate information about salt fluoridation, which are especially damaging to the poor and underserved (*1*), include:

- A public uninformed or misinformed about available measures of self-protection.
- Failure of individuals and society to benefit from scientifically valid health measures.
- Harm caused by underuse or inappropriate use of fluoride.
- Needless illness, such as dental caries, and associated social and financial costs for the public.

[1]This chapter was written by Alice M. Horowitz, PhD, National Institute of Dental Research, National Institutes of Health, United States Department of Health and Human Services.

Thus, providing science-based health information in an effective manner for use by individuals and communities is an essential ingredient for reducing morbidity and mortality and improving the quality of life. To that end, a few definitions are in order.

Health education is "any planned combination of learning experiences designed to predispose, enable, and reinforce voluntary behavior conducive to health in individuals, groups, or communities" (*2*). Education is required at all stages of starting and continuing any health measure. Education about the need to use caries-preventive agents such as fluoridated salt is especially important. While tooth decay often is considered inevitable, and is nearly ubiquitous among some groups, those affected by the disease often do not know how it can be prevented.

Education suitable for all audiences is essential to gain acceptance of a community-based intervention such as salt fluoridation. Thus, all educational materials—whether printed, electronic, or verbal—must be tailored to the specific intended audience. For example, salt fluoridation educational materials designed to train health care providers would not be the same as those meant for the general public.

Health promotion is "any planned combination of educational, political, regulatory, and organizational supports for action and conditions of living conducive to the health of individuals, groups, or communities" (*2*). Such 'supports' change the environment in ways that improve health, even in the absence of an individual's actions, *or* they enable individuals to take advantage of a preventive regimen like fluoridated salt by removing barriers to its use. Making fluoridated salt available in communities where the level of fluoride in drinking water is scant is one example of health promotion.

Health communication is the art and technique of informing, influencing, and motivating individuals, institutions, and communities about important health issues. Health communication is a tool for disease prevention, health promotion, health education, health care policy-making, and for providing health care (*3*). Health communication takes place through many channels, in homes, in schools, at work, and in the street.

Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (*3*). In the context of salt fluoridation, health literacy means understanding about the role of fluoride in preventing or reducing dental caries.

Primary prevention refers to a procedure or course of action that prevents the onset of disease (*4*). Appropriate use of fluoride by health care providers and individuals, and encouragement of its use in community-wide programs is a primary preventive measure. For example, the implementation of fluoridated salt or community water fluoridation is a primary preventive measure. In contrast, restoring or filling a tooth is a secondary preventive measure because it arrests or treats disease after it has already occurred.

WHY EDUCATE ABOUT SALT FLUORIDATION?

All too often, lack of understanding of a health procedure creates confusion, fosters suspicion, and stimulates myths and untruths. Thus, when implementing a preventive procedure, especially a community-based procedure like salt fluoridation, education of *all* groups involved in the adoption process is necessary. For example, misunderstanding about fluorides can arise in communities where too much fluoride naturally occurs in drinking water, causing fluorosis. People in such communities may not recognize the benefits of using fluoride at lower doses. Another reason for salt fluoridation education is to counter misinformation spread by groups that oppose the use of fluoride at any level, including at safe levels to prevent tooth decay. Although anti-fluoride groups have largely focused on opposing community water fluoridation programs and have not attacked the use of fluoridated salt, such opposition should be planned for by educating individuals and communities about the benefits of appropriate fluoride use.

WHO NEEDS TO BE EDUCATED ABOUT SALT FLUORIDATION?

Implementing and continuing the use of salt fluoridation requires education of not just the public at large, but of health care providers, public health officials, elected officials, salt manufacturers, salt plant operators, and members of the mass media (*5*).

PRINCIPLES AND METHODS FOR EDUCATING ABOUT FLUORIDATED SALT

Many skills are needed to spread knowledge about salt fluoridation. These include seeking information, planning, organizing, informing, listening, demonstrating, leading, guiding, and providing reinforcement and feedback. These activities help individuals and communities understand the need for an effective preventive measure against dental caries. Often, people in low-income groups feel helpless and believe that they cannot control events in their lives. But such individuals should be persuaded that dental caries is *one* disease they *can* control. Knowledge about the disease and what is available to fight it provides the understanding necessary for them to take appropriate action.

Principles Applicable to Salt Fluoridation Education Include:

- Education must be an integral part of any legislation, regulation, or service.
- Education is needed to reinforce understanding and gain acceptance for the procedure.

- The content of education must be accurate and based on the most recent scientific evidence.
- Educational materials such as leaflets, films, DVDs, and slides about salt fluoridation are *aids* to understanding. Educational materials alone are not a preventive regimen.
- Educational materials must be designed for specific ethnic, cultural, and age groups. They should be field-tested prior to final development.
- Educational materials are most effective when they focus attention on one topic (such as salt fluoridation), provide reinforcement on the subject, or foster discussion in group sessions.
- Educational materials should only use plain language to facilitate understanding among user groups (*6–10*).

Using Plain Language

When communicating about salt fluoridation, you must use plain language in printed materials, billboards, fact sheets, in television or radio announcements, in group sessions and in one-on-one communication. Avoid dental jargon. For example, rather than 'dental caries,' use the terms 'tooth decay' or 'cavities.' State information in short, simple sentences and paragraphs, and use the active voice. This approach may be difficult for health care providers, including dental care providers, to grasp and apply because of their academic or technical training. But when educating the public about any medical or dental procedure, we must communicate in plain, clear language to achieve understanding of all groups (*6–10*). Using medical and dental terms unfamiliar to our audiences stifles the educational process and may hinder implementation of the preventive intervention we are trying to introduce.

Methods Applicable to Educating about Salt Fluoridation

Multidimensional approaches to health promotion have been shown to be much more effective than using a single approach. Well-planned educational programs for communities usually use more than one of the following broad approaches:

- *One-on-one or interpersonal communication* when discussing the need for salt fluoridation with community policymakers and salt manufacturers.
- *Group presentations and discussion* about fluorides for training health care professionals about salt fluoridation. Group presentations might also include town hall meetings or visits with parent groups, or training mothers to teach other parents about salt fluoridation.
- *Community organization*, such as establishing a committee to provide guidance for the salt fluoridation program or a committee to obtain epidemiologic data for program managers about the need for caries prevention before salt fluoridation is initiated.
- *Mass communication*, tapping newspapers, television, posters, kiosks, websites and radio to inform the public about the need for salt fluoridation or to reinforce knowledge and understanding about the effectiveness of a given regimen (*5*, *7*).

WHAT TO TEACH ABOUT FLUORIDES

Everyone needs to know what fluoride is and how it prevents dental caries, as well as about various methods of fluoride application and appropriate combinations of toothpastes, oral rinses, or water supplements containing fluorides and their relative effectiveness. Box 4.1 briefly explains what needs to be taught about fluorides. It is equally important to teach that too much fluoride can and should be avoided. Table 4.1 provides a list of fluoride agents that can be used safely in combination with fluoridated salt, by age group.

WHAT TO TEACH ABOUT SALT FLUORIDATION

Box 4.2 provides information that should be taught about salt fluoridation. Everyone needs to know what salt fluoridation is and how it works, as well as the benefits of using it. Also, everyone needs to know that we must practice good oral hygiene, reduce the frequency and number of sweets, and go to a dentist periodically. Using fluoridated salt does not mean that other important dental health procedures should be abandoned.

BOX 4.1 What Everyone Needs to Know About Fluorides

- Fluoride is a natural element found in the earth land mass and, in varying amounts, in all water.
- Appropriate and continuous use of fluoride is the best method of preventing tooth decay throughout life.
- Fluoride can be used by children, adults, and the elderly.
- Fluoride protects teeth from decay in two ways:
  1. During tooth formation, fluoride is incorporated into the tooth structure, making it more resistant to decay (referred to as systemic fluoride).
  2. After tooth eruption, fluoride remineralizes areas of the tooth that have been demineralized (referred to as topical fluoride).
- Fluorides are available in a variety of products.

TABLE 4.1 Topical fluoride regimens that can be used in combination with fluoridated salt.

Agent	Ages	Recommendation
Fluoride toothpaste	2–6 years	Use only a pea-size amount. Do not swallow
	6 years and older	No restrictions.
Fluoride mouthrinse	6 years and older	No restrictions.
Professionally applied fluoride	Based on individual needs either annually or semi-annual applications.	

Caution: Fluoridated salt should not be used in combination with community water fluoridation or dietary fluoride supplements.

BOX 4.2 What Everyone Needs to Know about Fluoridated Salt

- The use of fluoridated salt to prevent tooth decay is well-documented by scientific research.
- Fluoridated salt is an equitable public health procedure that benefits all people, regardless of age, socioeconomic status, or access to dental care.
- Fluoridated salt is safe, effective, and used in many countries around the world.
- Fluoridated salt provides both topical and systemic fluoride benefits.
- The process of adding fluoride to salt is similar to that of adding iodide to salt.
- The use of fluoridated salt saves teeth and cuts dental bills.

WHO SHOULD PROVIDE EDUCATION ABOUT SALT FLUORIDATION?

Health care professionals, including but not limited to dentists, physicians, nurses, pharmacists, and health educators should be the primary teachers of other health care providers and of the public. This is because, due to their health-related training, these professionals are believable and are respected in their community. But, just because they have their respective degrees does not mean that they are knowledgeable about fluoride or salt fluoridation. Thus, health care professionals need to acquire accurate information to ensure that they are imparting science-based information and that their messages are as consistent as possible.

In addition, trained health care providers can educate other professionals outside the sector who, in turn, can help educate the broader public. For example, mothers can be taught to educate other parents about fluorides. We need these education 'extenders' to help inform the entire population. 'Each one teach one' is an approach many communities use to share health information. These community health educators may be especially useful in rural areas. Consequently, they must be well-informed and receive periodic educational reinforcement.

The Role of Health Professionals in Educating about the Need for and Benefits of Fluoridated Salt

Health professionals have multiple roles in educating a community about salt fluoridation. First and foremost, they must be well-informed. The public expects health professionals to be experts in health matters, and to advocate for preventive procedures on the basis of well-documented evidence. In addition, health professionals are expected to provide accurate information in a variety of settings, to average citizens as well as to community leaders. Dental professionals may take a leading role in implementing and sustaining salt fluoridation, or they may choose to assist others involved in the process. They may be consultants or primary educators of community members. Their role includes helping to overcome barriers to implementing preventive procedures, such as working with salt manufacturers and processors to ensure fluoridated salt is available in the marketplace. Our role as health care providers is to be proactive and to support preventive procedures.

Health professionals also need to be well-versed about salt fluoridation because they may work with the mass media in different capacities. For example, health professionals may be interviewed on radio or television or for a newspaper, or may be asked to write an editorial for a local newspaper. Cultivating relationships with news media representatives is an important strategy for health communication.

THE NEED FOR CONTINUOUS EDUCATION ABOUT SALT FLUORIDATION

Education about a preventive health regimen is not a one-shot effort, but must be continuous. The reason is simple: each new generation needs to learn important health information. Just as new parents must be taught about the need for early childhood vaccinations, those novice parents also need to learn about the appropriate use of fluorides. Also, all of us benefit from having education reinforced periodically, especially on health matters, particularly as new or updated information becomes available.

PLANNING AND STRATEGY DEVELOPMENT

A plan is a detailed scheme to implement strategies to accomplish specific objectives. In this case, we want to increase understanding about the need for fluoridated salt, make that salt available, and ensure that it is used appropriately. A small group representing all potential partners in the process, including representatives from the community, should draft the plan. People with formal training in communications should be involved in this planning process; these expert communicators can be found in educational institutions, private industry, and in the mass media. Once the plan is drafted to the planning group's satisfaction, it should be shared with the larger group of partners (*5–7*). A written plan of action that includes a timeline will help everyone understand:

- Specific objectives and long-term goals of implementing salt fluoridation.
- Roles and responsibilities of each group or individual.
- Partners needed in the process.
- Strategies needed to reach each audience.
- Specific channels of communication (print materials, radio, TV, Web sites, posters, etc.) and content for each target audience.
- Specific materials to be developed and how they will be distributed.

- Specific messages for each audience.
- Meeting sites for the organizers and other specific audiences.
- Available resources.
- Barriers and constraints.
- Priorities.
- Evaluation process.

A written plan of action helps everyone involved in the project stay on track to achieve objectives. The plan also can be used to inform others about what is being done and to enlist new partners. Such a plan also can be used to help get resources to cover costs for some of the promotional materials.

SUMMARY

Education is essential for promoting optimal fluoride use by health care providers and the public. The educational role of health care providers, especially dentists, may be quite diverse. First, health care providers need to be well-informed and may need special training on salt fluoridation. They need to be advocates for salt fluoridation, and they must be able to communicate at the appropriate level for individuals or groups. These trained health care providers will teach other health professionals about fluoridated salt and they may educate members of the public. Finally, they may be called on to discuss the topic with legislators or members of the media. Like any other preventive health regimen, implementing salt fluoridation in a community or nation requires education every step along the way. A written plan of action is necessary to achieve the collective objectives.

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5. SALT PRODUCTION AND TECHNOLOGY DEVELOPMENT FOR SALT FLUORIDATION[1]

INTRODUCTION

The population of the countries of the Region of the Americas reaches nearly 800 million persons. The nations of North, South, and Central America, and the Caribbean encompass the full spectrum of social and economic development and infrastructure. Countries such as the United States of America and Canada are among the world's most developed, and their populations enjoy high levels of wellness and good health care. The opposite is true of countries such as Haiti, Bolivia, and Nicaragua, where extreme poverty is reflected in the state of health care and services their populations receive. This is especially true in regards to oral health and oral health services. For most countries of the Region, scant resources make it nearly impossible to tackle the high incidence of caries.

The discovery of fluoride as a preventive agent for caries, and the subsequent development of water fluoridation (first used in Grand Rapids, Michigan, in 1945) led to the hope of widespread implementation of water fluoridation. However, in underdeveloped countries where water supply and distribution systems are generally decentralized and inadequate, water fluoridation proved impractical. Although the use of iodized salt enjoyed widespread acceptance, the seemingly obvious anticaries solution—to use salt as a carrier for fluoride as it was already being used for iodide—was not put into effect until 1955, when Switzerland became the first country to implement salt fluoridation.

The use of fluoridated salt in Switzerland and of fluoridated water in the United States and other developed countries, as well as fluoridation's success in decreasing caries prevalence rates, led to a landmark study conducted in 1967 by PAHO, the National Institute of Dental and Craniofacial Research, and the University of Antioquia in Medellin, Colombia.[2] That study established that the use of fluoridated salt could have the same anti-caries effect as fluoridated water. As a fluoride vehicle, salt was shown to be as reliable and convenient as water.

This was an important discovery, because efforts to promote water fluoridation in the Americas often had failed. Notable water fluoridation efforts in the Region include the following:

- Guatemala City began fluoridating most of its water supply in 1983. However, there were periods over the years when the system did not function for a variety of reasons, including financial inability to purchase fluoride. The city's

[1]This chapter was written by Trevor Milner, Salt Fortification Consultant, Pan American Health Organization.

[2]Study conducted by University of Antioquia, in Medellin Colombia and sponsored by PAHO, NICDR and W.K. Kellogg Foundation during 1963–1972.

water fluoridation program has since been abandoned.

- Jamaica tried to implement water fluoridation in Kingston in the 1970s. Although fluoridation equipment was purchased, the system was never implemented due to operational costs.
- Beginning in 1975, Panama's Canal Zone had fluoridated water, as did parts of Panama City. Since 2000, budgetary constraints have made it increasingly difficult to operate the water fluoridation system.
- Chile's municipal centers have had water fluoridation since the 1980s. The system in Chile operates well, and about 65 % of the country's population is covered.
- Some of Argentina's main cities, such as Buenos Aires and Rosario, have fluoridated water. But the system is confined to urban areas and operates inconsistently.
- In Brazil, São Paulo distributes fluoridated water to about 65% of its 7 million inhabitants.

The overall failure to establish water fluoridation in Latin America and the Caribbean was mainly due to the absence of large, centralized water supply systems and problems due to lack of funds for installing and operating fluoridating systems. Even in countries that were able to install and operate water fluoridation systems, coverage did not exceed 65% of the population.

The realization that water fluoridation was not feasible for many countries, and the success of the Medellin study, set the stage for the all-out promotion of salt fluoridation in the Region. The objective was to deliver appropriate fluoride levels to the population in order to diminish the rate of dental caries in a cost-effective fashion.

In response, PAHO embarked on a program to encourage suitable countries to implement salt fluoridation in the early 1980s. In 1985, Jamaica became the first country in the Americas to implement salt fluoridation on a nationwide scale. Costa Rica quickly followed, as did several other countries. It was clear that enlisting the cooperation of the Region's salt industry would be critical for the success of any salt fluoridation efforts. To that end, PAHO set out to gather as much information about the characteristics of the salt industry in the Americas. Existing programs of salt iodization that had already proven successful in the battle against iodine deficiency diseases became the first building block for the development of a successful salt fluoridation strategy in the Region.

- Eighteen countries in the Region have salt fluoridation programs at various stages of development.
- Five countries (Colombia, Costa Rica, Jamaica, Mexico, and Uruguay) have fully sustainable programs.
- Eleven countries—Belize, Bolivia, Cuba, the Dominican Republic, Ecuador, Honduras, Nicaragua, Panama, Paraguay, Peru, and Venezuela— are in an advanced stage of implementing salt fluoridation programs.
- Three countries (El Salvador, Guatemala, and the Bahamas) are beginning to implement programs; Guyana and Grenada are projected to embark on salt fluoridation efforts soon.
- Almost 200 million people in the Region are exposed to sustained, appropriate intake of fluoride via salt. Ultimately, an additional 125 million people will have an appropriate fluoride intake using salt.

This success has been in no small measure due to the cooperation and assistance from the hundreds of the Region's salt producers. This chapter presents an overview of the production, quality, and marketing of salt in the Americas, especially as it relates to fluoridated salt.

GLOBAL AND REGIONAL SALT PRODUCTION

Total worldwide production of salt—including by solar evaporation of seawater or inland brines, mining underground and surface rock salt deposits, and gathered as brines, mainly by solution mining—was 225 million tons in 2002.[3] Table 5.1 shows the world's top 15 salt producers. Table 5.2 shows salt production by continent, demonstrating that the Region of the Americas is a major contributor to the

[3]United States Geological Survey, Mineral Commodity Summaries, January 2003.

TABLE 5.1 Top 15 salt producers, worldwide, 2002.

Rank	Country	Salt production, including salt in brine (in 1,000 metric tons)	Percent of world production
1	United States of America	43,900	19.5
2	China	35,000	15.6
3	Germany	15,700	7.0
4	India	14,800	6.6
5	Canada	13,000	5.8
6	Australia	10,000	4.4
7	Mexico	8,700	3.9
8	France	7,100	3.2
9	Brazil	7,000	3.1
10	United Kingdom	5,800	2.6
11	Poland	4,300	1.9
12	Italy	3,600	1.6
13	Spain	3,200	1.4
14	Russia	3,000	1.3
15	Ukraine	2,400	1.1
	All Others	48,000	21.3
	Total	225,000	100

Source: United States Geological Survey, Mineral Commodity Summaries, January 2003.

TABLE 5.2 Global salt production, by continent, 2004.

Continent	Production (in 1,000 metric tons)	Percent of total
Europe	87,100	38.7
North America	68,200	30.3
Asia	45,200	20.1
Central and South America	13,200	5.9
Oceania	7,200	3.2
Africa	4,100	1.8
Total	225,000	100

Source: Data from the Salt Institute (www.saltinstitute.org)

world's salt production. The Region as a whole accounted for 36.2 %, or 81.4 million metric tons, of world production. Four of the world's top ten salt producers (the United States, Canada, Mexico, and Brazil, in descending order) are in the Americas. Total salt production in the 17 Latin American and Caribbean countries that will be examined in this chapter amounts to 10.2 million tons per year, representing 13% of salt produced in the Americas and 5% of salt produced worldwide.

Salt Production Methods

Crude salt production methods include surface mining, underground mining, solution mining, and solar evaporation of seawater. Worldwide, most production is done by solar evaporation (see Table 5.3). In Latin America and the Caribbean, the vast majority of salt production is by solar evaporation of seawater; the second most-used method is solution mining of underground salt deposits. Vast resources of salt (easily accessible by surface mining) in Bolivia, Chile, northern Argentina, and southern Brazil are barely exploited.

Surface mining involves the collection of salt deposits at or just below the earth's surface. In some cases, small-scale producers simply dig up blocks of salt, or use forks or spades to collect rock salt. Large-scale surface mining relies on heavy equipment such as diggers and front-end loaders that scrape the salt into heaps and then load it on trucks or railcars for transport.

Solution mining requires the use of hot water pumped deep underground to dissolve salt deposits. The resulting salt solution, or brine, is then brought to the surface and the salt extracted from the solution by evaporation. Sometimes the brine is used directly in other chemical or industrial processes, bypassing the salt extraction stage. Used extensively in Mexico and parts of the United States, solution mining is a highly industrial process requiring large capital expenditures in plant and equipment. Energy requirements also are high to heat the water for

TABLE 5.3 Salt production worldwide, by production method, 2004.

Salt type	World production (in metric tons/year)	Percent of total
Solar evaporation of seawater or inland brines (solar salt)	83,000,000	36.9
Rock salt (surface and underground)	67,000,000	29.8
Solution mining (brines)	75,000,000	33.3
Total	225,000,000	100

Source: Salt Institute (www.saltinstitute.org)

salt dissolution and then to evaporate the water for salt precipitation.

Underground mining, once used extensively in Latin America, has now been outstripped by other production methods. It involves digging out salt from large underground deposits.

Sea salt production uses the natural process of evaporation. Seawater (with about a 3% concentration of salt) is captured in a series of ponds and, from exposure to wind and sun, evaporates in stages, yielding a saturated solution of about 33% salt concentration. The salt is then precipitated in special ponds (called crystallizers) and then reaped by large machines. The salt may then be washed or sent to processing plants for refining or hydro-washing. The world's largest solar salt plant is at Los Cabos, in Baja California, Mexico. Other large solar salt plants are located near Merida, in Mexico's Yucatan Peninsula; near Barcelona, Venezuela; on the island of Bonaire in the Netherlands Antilles; and in Inagua in the Bahamas. The process can also be used by small producers that rely on manual or minimally mechanized processing.

All the crude salt production processes described above can be found in the Region. The choice of one over another depends on a number of factors, including:

- The availability of the salt raw material—whether it lies in surface deposits, underground salt deposits, underground brine deposits, or the sea.
- The history of salt production in the country or region; the degree of sophistication and development of salt producers; and producers' access to capital, equipment, and technology.
- The country's overall economic development level and its level of industrialization.

Large-scale producers using sophisticated technology and equipment are found in Mexico, Venezuela, Chile, Brazil, and Argentina. They rely on various methods, from solar evaporation to surface mining. Smaller-scale producers using lower level technology and relying on more manual techniques can be found in Central America and the Caribbean, with one or two exceptions such as the Bahamas and Bonaire.

Salt Processing

Salt used for direct or indirect consumption by humans or animals accounts for only about 7% of total salt production. Most salt is used as a raw material in the manufacture of other chemicals or products. Large quantities of crude or rock salt also are used for highway de-icing in the United States, Canada, and European countries. Salt used in foods or as a condiment in the home normally undergoes some form of processing, which may involve washing or purification of the salt, drying, and reduction in the size of salt granules, as well as the addition of dehumidifiers or free-flow agents and other additives such as iodide and fluoride. Processing plants or factories of varying sizes and sophistication are therefore used to carry out these processes before salt intended for human or animal food is distributed to wholesalers, retailers, and individual consumers.

There are many salt processors in the Region of the Americas, ranging in size from those processing more than 500,000 tons per year (Bahamas, Bonaire in the Netherlands Antilles, Brazil, Colombia, Chile, Mexico, and Venezuela) to medium-scale producers that yield 250,000 tons per year, to small-scale producers that yield 2–5 tons per year. Small-scale producers tend to be found in Central America, South America's Pacific Coast, and the Caribbean, where the tradition of salt making is centuries old. Table 5.4 shows the distribution of producers by production type and of processors by size for the 17 countries that are the focus of this chapter. Although the Bahamas and Bonaire (Netherlands Antilles) are large-scale salt producers, almost all of their production is exported and is not locally processed.

Three different methods are mainly used to process salt—salt refining, salt hydromilling (or hydrorefining), and the mill-package process.

Salt refining produces salt of a regular particle size and the highest purity, typically 99.8% sodium chloride, 0.005% insolubles, 0.10% chemical impurities, and 0.002% moisture. Capital and energy intensive, the process is normally used to extract salt from brine produced in solution mining. Salt refining is also used to process salt produced by other methods, such as solar evaporation and surface or underground mining.

In salt refining, salt is first dissolved, and the resulting brine solution purified by filtration and the addition of chemical flocculants. The purified brine is then heated and evaporated in a series of machines known as multi-effect evaporators. The saturated brine solution is then crystallized, and the resulting salt is dewatered and dried. At the point of drying, various chemicals may be added, such as potassium ferrocyanide (an anticaking agent otherwise known as YPS) or sodium aluminum silicate (an antihumidifying agent). At this time, iodide in the form of potassium iodide or potassium iodate and fluoride in the form of potassium or sodium fluoride may also be added. Figure 5.1 demonstrates the process. Large manufacturers of salt from underground solution mining, such as Sales del Istmo in Coatzacoalcos, Mexico (see Figure 5.2) use this process. This process also is used in Colombia, the Dominican Republic, and Venezuela.

The hydrorefining process (also known as the hydromilling process or mill wash-and-dry process), also produces good quality salt. (See Figure 5.3.) However, the salt is less pure than that produced by the refining process.

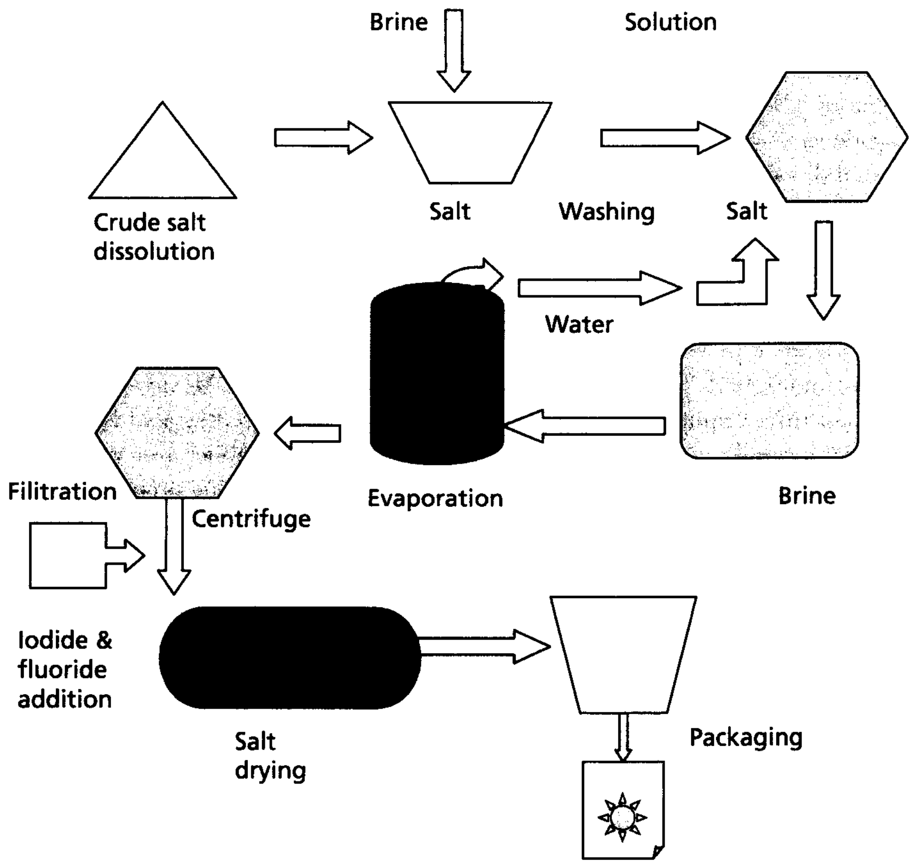
First, crude salt is milled and simultaneously washed with clean saturated brine solution. This removes most dirt and other insoluble particles. Milling

TABLE 5.4 Salt production and processing in countries with a program of salt fluoridation, 2000.

Country	Population (in millions)	Total crude salt production (in 1,000 tons/year)	Production by type (in 1,000 tons/year)		Salt consumption (in 1,000 tons/year)			Number of salt processors by size		
			Solution mining	Solar evaporation	Total	Direct human consumption	Fluoridated salt	Large-scale (> 100K tons/year)	Medium-scale (100–20K tons/year)	Small-scale (< 20K tons/year)
Bahamas	0.3	1,000		1,000						
Bolivia	8.9	50	0	0	45	30	2	0	0	42
Bonaire (Netherlands Antilles)	0.2	750		750						
Colombia	44.2	1,400	600	700	500	140	70	3	5	50
Costa Rica	4.2	20	0	20	18	13	10	0	2	0
Cuba	11.3	100		100					4	0
Dominican Republic	8.7	50	0	32	53	30	0	0	0	80
Ecuador	13.0	75	0	75	75	44	36	1	2	10
Guatemala	12.3	60	0	60	58	40	0	0	0	150
Honduras	6.9	42	0	42	50	21	0	0	0	250
Jamaica	2.6	2	0	2	16	12	12	0	1	0
Mexico	103.5	8,700	800	7,900	1,600	350	250	3	6	10
Nicaragua	4.5	52	0	52	52	16	0	0	0	300
Panama	3.1	18	0	18	30	11	0	0	1	55
Peru	27.2	180	0	180	100	87	40	1	2	50
Uruguay	3.4	0	0	0	40	11	9	0	3	2
Venezuela	25.6	805	0	805	615	85	60	2	2	10
Total	279.9	13,304	1,200	11,736	3,252	888	487	10	28	1,009

Source: Pan American Health Organization.

FIGURE 5.1 Salt evaporation refining process.



also reduces the size of the salt particles (solar rock salt consisting of 1–2 inch particles is typically used as raw material). After the initial washing, the salt falls countercurrent to brine through an elutriation column. This reduces levels of chemical impurities such as magnesium, calcium, carbonates, and sulfates.

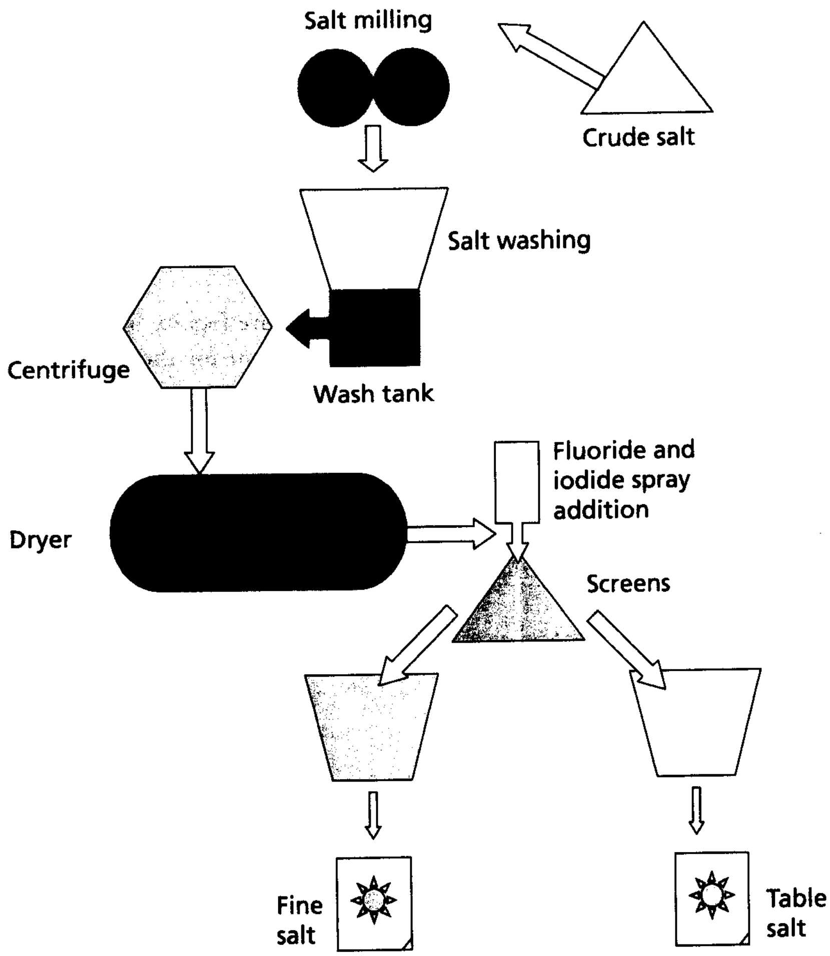
The washed salt is then dewatered, usually in a centrifuge, although some refineries use simple systems such as draining in piles or in tumble screens. Next the salt (now at 8% to 10% moisture) is dried in a dryer. Just prior to drying, potassium ferrocyanide is added. Iodide and fluoride also may be added at this point.

Before being packaged, the dried salt is screened to separate it into different size fractions. Coarse salt is normally bulk packaged for both food and nonfood industrial use. Medium-grain salt is usually intended as table grade salt (a dehumidifying agent such as sodium aluminosilicate may be added prior to packaging). Finer-grain salt is used in food processing to make brine solutions for canning and by the baking industry.

FIGURE 5.2 "Sales del Istmo" evaporative salt refinery, Coatzacoalcos, Veracruz, Mexico.

Hydrorefining or some variant of it is used by the vast majority of salt processors in the Region, espe-

FIGURE 5.3 Schematic presentation of the salt hydrorefining process.



cially if the raw material is solar salt. The popularity of the process is due to the lower capital and energy costs associated with it. Quality can be as good as 99.2% sodium chloride, 0.15% insolubles, 0.25% chemical impurities, and 0.25% moisture. Figure 5.4 shows a plant in Panama that uses this process.

The third common salt refining process is the mill-and-package method, which is favored by small-scale producers and requires a minimum of machinery and technology. It also results in salt of the lowest quality, with greater variation of particle size and high levels of moisture and impurities.

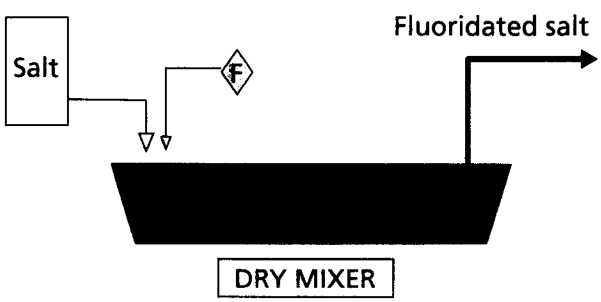
Raw material for the process, usually solar or surface-mined salt, is first milled to reduce particle size (mills are usually locally manufactured hammer mills). The milled salt may in some instances be dried, normally by a tray type dryer as shown in Figure 5.5. At some point in the process, usually directly after milling, iodide and fluoride are added by the dry method.

The mill-and-package method is widely used in Guatemala, Honduras, and Nicaragua. Packaged salt quality can be as good as 95% sodium chloride, 1% insolubles, 1% chemical impurities, and 3.5% moisture, depending on the treatment and raw material used. Use of surface-mined salt usually yields a lower moisture content. If solar salt is used, washing and draining the salt after harvesting improves its quality.

Unfortunately, the problem is that countries with underdeveloped salt processing most often use the mill-and-package refining. This frequently results in salt that is below acceptable standards for fortification with iodide or fluoride. Therefore, emphasis must be placed on upgrading salt processing facilities in these countries.

FIGURE 5.4. Dryer at a hydrorefining salt plant in Panama.

FIGURE 5.5 Schematic presentation of the dry method of salt fluoridation.



PRODUCTION OF FLUORIDATED SALT

When a fluoride compound is added to salt, it is expected that it will be done in such a way as to reach a consistent level of fluoride ion in the salt and to do so in a cost-effective, efficient, and convenient manner without affecting the taste, appearance, flowability, or shelf life of the packaged salt. To this end, the nature of the fluoride chemical and the properties of the fluoride ion at the desired concentration must be considered, as well as the method of addition and other operational aspects of the fluoridation process.

The addition of fluoride to salt is accomplished by the wet method or the dry method, both of which are used throughout the Region. The wet method is usually used for medium- to large-scale continuous dosing. The dry method is usually used in small-scale to medium-size batch operations. Bear in mind that the processing and fortification of salt with iodide and fluoride is an industrial process. The procedures, safeguards, and quality standards required for a modern industrial process need to be built in and adhered to in order to ensure the successful and consistent manufacture of fluoridated salt. Regardless of the process used to fluoridate salt, the following systems and facilities are required:

- A secure facility for storing fluoride chemicals.
- A system for the measurement and control of the amount (weight) of fluoride for a given weight of salt.
- A system for measuring and controlling the amount of salt.
- A system to ensure dispersion of the fluoride compound throughout the salt and homogeneity of the salt-fluoride mixture.
- A quality control system that includes both data collection and process monitoring as well as equipment to analyze and record the concentration of fluoride in the salt.

The processes themselves are simple. For the dry method, a fluoride chemical is added to salt in the proportion required and then mixed thoroughly. For the wet method, the fluoride chemical is dissolved in water and sprayed on a known quantity of salt in the proportion required; thorough mixing results in fluoridated salt. For each method the standard procedures to make fluoridated salt are:

1. Calculate the required amount of fluoride chemical that, when added to a unit weight of salt, will result in a fluoride ion concentration of 200 to 250 ppm.
2. Measure this quantity of fluoride chemical.
3. Add to a unit quantity of salt, dispersing the fluoride as much as possible
4. Mix well.

Fluoridation Chemicals

The chemicals used in the fluoridation of salt and their relevant properties are shown in Table 5.5.

Either of two chemicals are added to salt to produce fluoridated salt—sodium fluoride (NaF) in the

TABLE 5.5 Chemicals used in the fluoridation of salt, their formulas, and relevant properties.

	Sodium fluoride	Potassium fluoride	Potassium fluoride anhydrous
Formula	NaF	KF_2H_2O	KF
Molecular weight	42.0	94.13	58.13
Solubility (gm/100ml)	4.1	100	55
Price (U$/kg)	2.5–5.0	2–10	1–8
gm required per ton of salt	581	778	1,238
Cost added per ton of salt	2.76	7.63	9.91

dry method or potassium fluoride (KF) in the wet method. There is also a hydrated form of potassium fluoride (KF_2H_2O).

The Dry Method

In the dry method, weighed amounts of sodium fluoride are added to a known batch weight of salt. As fluoridation and iodization of salt are usually done at the same time using the same equipment, premixes are usually made. (See Figures 5.6–5.7.) Premixes consist of sodium fluoride, potassium iodate, calcium carbonate, and refined undosified salt. The premix formula is calculated so that the target concentration of fluoride and iodide is achieved when the premix weight is added to the batch. Premixes are often made by mixing the sodium fluoride and salt with an existing, commercially available premix called "yodo-cal." Yodocal is a mixture of eight parts-by-weight calcium carbonate and one part potassium iodate. The target concentrations are normally 225 ppm fluoride and 60 ppm iodide.

The premix addition is done in a salt mixer. Mixers vary from rotary paddle and rotary ribbon machines to rotating mixers and mixing cones, and are usually made of stainless steel. Mixer capacities range from 500 kg to 10 ton. A paddle mixer of 1–5 ton capacity, complete with motor, may be built in-house or at a local workshop for US$ 3,000–US$ 8,000.

The Wet Method

The wet method of fluoride addition uses a solution of potassium fluoride (potassium fluoride is required because of its high solubility relative to sodium fluoride). Solution concentrations can range from 10% to 55%, that is, saturated, or may even be

Figure 5.6 Dry method equipment: 500 lb capacity paddle mixer used for dry mixing of salt and fluoride and iodide additives.

Figure 5.7 Dry method equipment: 2 ton capacity rotary mixer used for dry mixing of salt and fluoride and iodide additives.

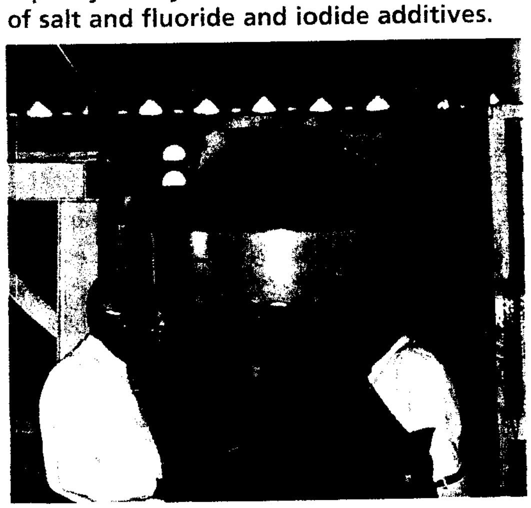
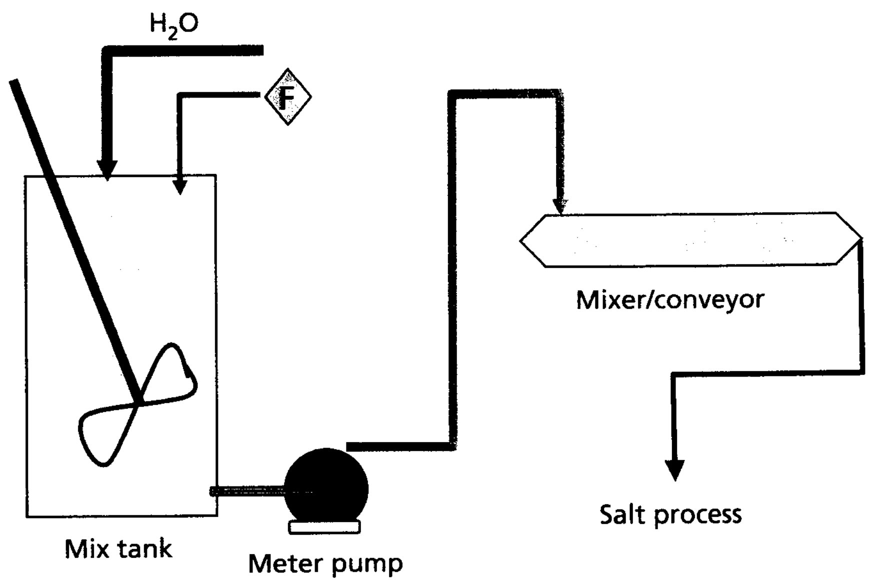


FIGURE 5.8 Wet method of salt fluoridation.



a slurry in a saturated solution. The solution, or slurry, is sprayed continuously at a controlled rate matched to a continuous flow of salt. The salt then passes through a mixer to ensure homogeneity. Mixers are of the continuous type—normally ribbon or screw stainless steel devices. (See Figures 5.8–5.10.)

Choosing between the Wet and Dry Methods

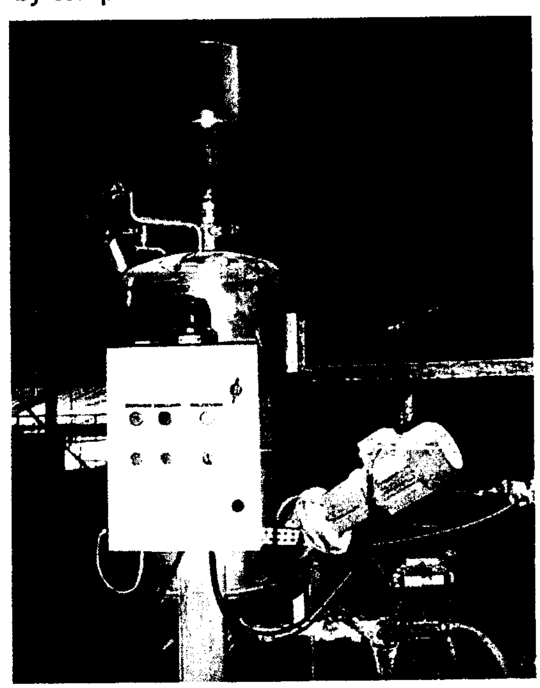
The choice between the wet or dry method of salt fluoridation depends on a number of factors, among them:

Scale and type of salt processing operation. For a small-stage or batch operation (under 10 tons per day), the dry method is preferable. For continuous processing operations, even those as small as 5 tons per day, the wet method is better.

Cost of equipment and chemicals. Equipment for the dry method usually costs less than equipment for the wet method. Sodium fluoride, the chemical of choice for the dry method, costs less than potassium fluoride, the chemical used for the wet method.

Quality. Applying the wet method to a continuous processing offers better control of the fluoride concentration.

FIGURE 5.9 Wet method equipment: dosing solution mixer and "egg" type pump driven by compressed air.



Obviously, availability of equipment and suitably trained personnel, existing plant layout and placement of new equipment, and overall ease of operations also should be considered.

FIGURE 5.10 Wet method equipment: fluoride/iodide dosing mixture trickles down on salt in large capacity ribbon mixer.

Quality Control Issues with Both Methods

The dry method is best suited to salt particles below 16 mesh size or 0.046 inches in diameter. With coarser salt, (greater than 16 mesh size) the fluoride powder tends to separate from the salt crystals. Over time, the fluoride sinks to the bottom of the salt packages, with the result that consumers receive uneven fluoride doses as they use up the package. ("Sal gruesa," for example, which is greater than 16 mesh size, should therefore not be treated with the dry method.

With the wet method, salt particles become coated with a layer of fluoride solution. On drying, the salt remains covered by a thin powder layer of fluoride. The wet method, applied to a continuous process, normally offers greater control of fluoride concentration. However, problems occur when a mixture of salt particle sizes is sprayed with fluoride solution to a target concentration, and then separated into different particle sizes for packaging. This is a normal occurrence in the salt hydrorefining process. Unfortunately, the separated salt particles will have different fluoride concentrations according to their size. For a target fluoride concentration of 200 ppm, actual values can range from 500 ppm for fine grain salt to only 100 ppm for the coarsest salt.

There are two reasons for this variation in fluoride concentration. Some of the fluoride chemical is shaken off of salt particles, during the process of size separation, and that loose fluoride powder remains with the finer salt particles. Also, fine salt is coated with a relatively greater amount of fluoride solution in the first place. This is because small diameter salt particles have a proportionally greater surface area than large diameter particles, and so, proportionally, more solution is deposited on the finer salt.

Therefore, it is important that a salt fluoridation system be closely tailored to the kind of salt plant in which it will be used, taking into account such factors as the salt process method, whether batch or continuous process is used, the plant's production rate, the types of salt produced and how the salt is to be packaged, and the types of salt to be fluoridated.

MARKETING OF SALT

The marketing of salt throughout the Region is changing. As is the case with many other products, the salt market was once highly protected in each country. Now, with reduction of trade barriers, intraregional trade in salt is increasing. Large, efficient processors are beginning to export their product, while processors that lag in quality and efficiency are increasingly concerned that imports will reduce their sales.

Production and consumption of salt for human consumption among the countries included in Table 5.4, increased from 888,000 tons in 2000 to about 1 million tons in 2004, more or less in line with population growth. Increased trade among these countries has increased more rapidly, however, doubling from 70,000 tons of salt for human consumption, or 8%, in 2000 to 150,000 tons, or 15%, in 2005.

National Salt Flows and Balance

In order to track the marketing of salt between countries of the Region, PAHO has developed a way of displaying the data to show the salt flows and balances in a particular country. From a public health perspective, this information is useful for determining the likely quantity of salt that could be imported from non-fluoridated areas or, conversely, the quantity of fluoridated salt that may be exported to countries that do not yet produce fluoridated salt locally. This kind of movement contributes to what is known as the

BOX 5.1 Venezuela's Successful Salt Industry

Venezuela's salt industry, which includes large and small processors, deserves a special look because of its efficiency and consistently high product quality.

The country has 14 salt processors. These facilities take crude salt, process it and package it, and then send it on to distributors. Large processors are Sal Bahia and Tecnosal, with capacities of 240,000 and 150,000 ton per year, respectively. Tecnosal has been in private hands for the last five years. The main medium and small processors are ALESCA, MOLISOCA and INDULSALCA, with capacities of 35,000, 18,000, and 24,000 ton per year, respectively. The two large producer-processors produce 250,000 tons per year, or 75.8% of total production of processed salt. The four medium processors account for 60,000 tons, or 18.2%, and the eight small and micro processors account for 20,000 tons, or 6.1% of the total.

The industry as a whole is considered to be mature and consolidated. As such, it is very difficult for newcomers to successfully produce and market new salt brands. Compared to most of the Region's countries, Venezuela has relatively few salt processors and only three crude salt producers. Most processors purchase crude salt from the source that offers the best price and the highest quality. The country overproduces crude salt, which results in a buyers' market and ensures competition and efficiency of operations among crude salt producers.

The processing operations are for the most part mechanized. Most processors use the hydrorefining process; INDULSALCA relies on the evaporative process and Sal Bahia uses both.

The quality of the finished salt product is consistently high. Chemical quality is on a par with similar products internationally and the packaging and presentation is very good. Sal Bahia's excellent canister salt product will soon be exported to the United States.

Since the Venezuelan salt market is highly competitive and the consumer relatively sophisticated, the secret of this industry's success has been management's recognition of the need to be efficient and to maintain high quality standards. The competitiveness of their product with regards to packaging, presentation, and price is constantly being emphasized.

Smaller processors continually strive to improve operations, adapting methods used by large producers. They modify existing equipment, and design and manufacture machinery at lower cost to fit their needs. For example:

- Design and manufacture inhouse of propane-fired rotary salt dryers: the dryer is inexpensive to construct, requires less energy to operate, and is virtually maintenance-free. Its cost is U$15,000, compared to a factory-made dryer of equal capacity, which would run U$100,000. Even though the locally manufactured dryer will last one-quarter of the time that the factory-made one will, it is more cost effective.
- Design and inhouse manufacture of milling systems. These are ingenuous and strike the engineering compromises best suited for the particular producer.
- Substitution of expensive centrifugal dewatering system by simple, inexpensive, and effective screw-and-drain pad dewaterer.

Venezuela's salt industry can serve as a model for many of the Region's smaller producers. PAHO has been encouraging other countries' processors to learn from the Venezuelan example.

"halo" effect—the beneficial effects of fluoridation in a country that does not fluoridate salt locally.

From a marketing perspective the information is useful to see the level of competitiveness of the salt trade in general. If there are many sources of salt entering a country, there is good reason to believe that the market there is highly competitive and that the local price of salt will reflect this competitiveness. Table 5.6 shows the salt flow for Venezuela.

Internal Marketing of Salt

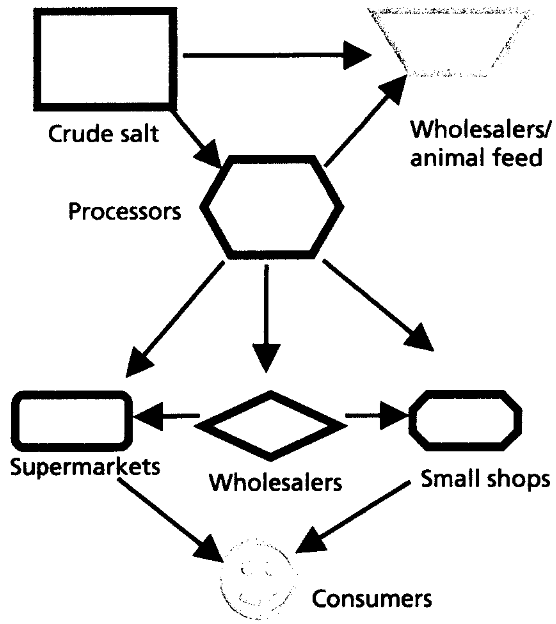
Mechanisms for marketing salt within countries are more or less the same Regionwide (see Figure 5.11).

TABLE 5.6 Salt flows and balance, Venezuela, 1999.

	Type/place	Quantity (tons/years)
	Crude, Bonaire	30,000
Imports	Processed, Colombia	5,000
Production	Solar salt	705,000
Imports + Production		740,000
Consumption	Direct human	85,000
	Food	145,000
	Industrial	385,000
Exports	Crude	70,000
	Processed	55,000
Consumption plus exports		740,000

Source: Pan American Health Organization.

FIGURE 5.11 Within-country salt distribution channels.



Even the Dominican Republic has changed its system in which a state-owned company (DISAL) used to purchase all crude salt produced and then distribute it to processors. This created an unnecessary middleman that added no value, reduced efficiency, and increased cost. Many processors in the Dominican Republic circumvented that system by importing crude salt directly from other countries. As of 2001, the system is now almost completely liberalized, with local processors acquiring inexpensive crude salt from the Bahamas, Venezuela, and Mexico.

The relative amounts of salt that go through each channel vary from country to country. Countries with a less developed salt industry will have more processing operations associated directly with crude salt producers. The processors would also develop their own network for distributing salt directly to small shops in a particular locality. In countries with large and competitive internal markets, each level of distribution is normally independent from the others.

Salt Prices

Salt prices vary widely throughout the Region. As may be expected, such variation is coming under pressure from liberalized trade and more open markets. In this changing environment, the more efficient producers, processors, and distributors will have an advantage. There is, however, a limit to the extent that they will dominate the industry, since a large component of the price of salt is the cost of transportation. Local salt producers close to the market will always have an edge over large producers. PAHO recognizes this, and will work closely with these processors to improve their quality and efficiency.

TABLE 5.7 Salt prices in US$/ton, selected countries in the Americas, 2000.

Country	Crude Salt (freight on board [FOB])	Refined/ packaged (marketplace)
Bolivia	8.00	180–120
Dominican Republic[a]	93.00	1,790–850
Honduras	45.00	210–417
Nicaragua	50.00	550–150
Panama[a]	83.00	630–550
Venezuela	12.00	350–100

[a] Prices have dropped rapidly since increased trade liberalization was put in place.
Source: Pan American Health Organization.

The Region of the Americas produces a considerable proportion of the world's salt, and the countries have good production and processing tradition and practices. Currently, the Region's salt industry is undergoing major changes as a result of trade liberalization. This change will bring improvement as well as disruption. In the end, the industry should be more vibrant, with surviving producers offering better quality salt to customers, and with improvements in both iodization and fluoridation. PAHO will continue to assist salt producers acquire information about salt processing, iodization, and fluoridation because of that technology's direct benefit to improved health.

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6. Strategic Planning for the Implementation of Salt Fluoridation Programs

Now that many salt fluoridation programs have been implemented, an understanding has emerged of a successful program's five major components: salt fluoridation cost-benefit analysis; country baseline studies to assess DMFT and exposure to fluoride; epidemiological surveillance systems for salt fluoridation, including biological and chemical monitoring of all fluorides, and quality control; salt-industry assessments; and evaluation and tracking systems to determine the effectiveness of nationwide fluoridation programs. PAHO has proposed the following three phases for implementing salt fluoridation programs (*1*).

- **Phase I—Feasibility and Program Implementation.** To determine whether a national fluoridation program may be appropriate in a given country, several preliminary studies must be conducted, including cost-benefit studies and prevalence baseline investigations of dental caries and fluorosis. Such studies can justify fluoride interventions, rather than other, less effective, interventions. Also, given economic constraints and market-oriented economies, conducting a cost-benefit analysis is one of the best ways to justify the implementation of preventive interventions such as salt fluoridation.
- **Phase II—First Evaluation.** Following baseline-data collection, PAHO recommends that the first evaluation of a salt fluoridation program should be done seven years after its implementation. After this time, early erupting teeth exposed to salt fluoridation throughout their development can be assessed for reduced caries and the prevalence of fluorosis. Long-term results, ascertained after 14 years, will subsequently measure the maximal caries-preventive effects and dental fluorosis in both early and later erupting teeth. Further biological monitoring (of caries and fluorosis) may be conducted after additional seven-year intervals.
- **Phase III—Long-term Evaluation and Consolidation.** Countries with salt fluoridation programs that have achieved DMFT scores at 12 years of age (DMFT-12) of 3 or less, have reached the consolidation stage. Nonetheless, continued monitoring and evaluation are needed to provide information on program progress, effectiveness, and sustainability, all of which are important to generate continued support for the program.

Certain assessments must be undertaken before beginning these phases. First, it must be clearly recognized—based on existing, immediately available information—whether or not there is a sound reason to reject the proposal to fluoridate salt. Second, it is important to gauge the political will of government and health authorities for undertaking salt fluoridation programs, for without that political will it will be difficult to mobilize resources. Experience has shown, however, that if objectives are clear, goals well-defined, and actions properly articulated, the political will for salt fluoridation and its acceptance by oral health care providers will follow. Once these considerations are taken into account, more in-depth studies may be justified, implying more costs, whose recovery will depend on the effective realization of the project (2).

PHASE I: FEASIBILITY AND PROGRAM IMPLEMENTATION

In the first phase, all data and information necessary to demonstrate the viability of a national salt fluoridation program should be developed for inclusion in the investment proposal that will be submitted to health planning and financing authorities. The proposal must identify technical and institutional problems to be resolved and the methodology to be applied for implementing salt fluoridation. This phase also entails conducting baseline studies that will provide a foundation for the scientific evidence required by the program. Baseline studies provide information on the disease that the program intends to address—in this case, caries—so that the ultimate effectiveness of preventive programs can be evaluated. The feasibility study also should consider economic and social factors, since they relate to the community's payment for and benefit derived from the program, and it should address aspects of implementation and operation.

Institutional Analysis and Cost-benefit Study of A Salt fluoridation Program

This study provides information on the feasibility of developing a salt fluoridation program in a country. To that end, such a study would collect existing information on dental caries, dental fluorosis, the scope of dental public health programs and available resources and facilities, general information on the salt industry, iodine programs, what institutions can assist in developing a salt fluoridation program, and whether a legal framework exists that would permit inclusion of fluoride or would facilitate development of specific standards for regulating quality and requirements for fluoride in salt for human consumption. The study also estimates expected costs and benefits of implementing salt fluoridation. A cost-benefit ratio would be obtained by assessing the economic resources that would no longer need to be spent on dental treatments after implementing salt fluoridation, in terms of dental caries prevalence, caries incidence, cost of dental services, program coverage, facilities available and other pertinent factors.

We will use the case of Bolivia to illustrate a cost-benefit study for salt fluoridation. Analysis of the economic feasibility of the program for fluoridating all salt destined for human consumption in that country used available data and estimated projections. Variables considered in that study could be applied to work to be done in other countries.

Conducting an economic evaluation of the use of fluoridated salt to prevent caries and other related oral disorders is an important step in determining the feasibility of implementing this intervention. The proposed methodology analyzes the expected costs and benefits of the intervention. The costs of the program are estimated in terms of what would be required to develop a system to manufacture and distribute fluoridated salt. The benefits are estimated in terms of reduced use of curative services due to the lower incidence of caries in a given period as a result of the salt fluoridation preventive program.

Bolivia's total population in 1994 was estimated at 7.2 million. The potential coverage with fluoridated salt was national, and annual salt consumption per inhabitant was approximately 3.65 kg (10g per day per person). The program to fluoridate salt for domestic consumption represents a modest investment of economic resources. Direct and indirect expenses (supplies and materials, equipment and machinery, technology, human resources) are relatively low, and do not require a large investment on the part of salt plants. In Costa Rica, for example, which has had a salt fluoridation program since 1987, the cost to produce the 15,000 tons of salt needed annually is approximately US$ 1.57 per ton or US$ 0.0016 per kg. This cost includes such categories as equipment maintenance and purchase of supplies.

The hypothesis proposed for this analysis is that the expected cost of salt fluoridation in Bolivia would be less than the benefit derived from reduced demand for public and private restorative services within a given time period and in a specific population. In other words, it is proposed that the use of fluoridated salt will achieve a significant savings of resources that would otherwise have to be invested in restorative services.

Costs of Producing Fluoridated Salt

The costs of producing fluoridated salt include the expected costs of implementing the program in Bolivia. These costs are presented in U.S. dollars, in order to control for the effect of inflation. Table 6.1 presents a calculation using the values for producing fluoridated salt by the dry method that were used in Costa Rica and the criteria issued by technicians in the salt industry. (For more detailed information on the dry method, please see Chapter 5, "Salt Production and Technology Development for Salt Fluoridation.") To arrive at the values in the table, the following factors were considered:

a) Installation of machinery and equipment in a selected salt plant is estimated to cost US$ 5,000 for the year of initiation (year 0).
b) Beginning with the first year of operation, an annual cost of US$ 2,000 is calculated for maintaining equipment and machinery, US$ 36,000 for personnel expenses (workers), and US$25,000 for training. These are operating costs of the 42 plants participating in the program; currently, these costs are covered mainly by the salt plants themselves (that is, they do not require fresh or additional investment).
c) An annual expense of US$ 19,600 is calculated for purchase of potassium fluoride, in a quantity sufficient to produce 35 tons of fluoridated salt per year. This quantity is estimated by taking into account the total demand for salt, in accordance with Bolivia's population size and the estimated daily consumption of salt by its inhabitants.

The expected total cost of producing fluoridated salt in Bolivia has been calculated as US$ 784,900 for the five years of the program, plus the year in which the program is launched. Of this amount, the costs of technological renewal at the plant level and the cost of fluoride (approximately $220,000) are considered to be recoverable. The cost of the machinery also is recoverable, because the financing mechanism could be similar to one already used in Bolivia's salt industry (CREDISAL)—through loans with generous repayment terms (soft loans) to the plants for amortization over a period of three years.

In an analysis by the Bolivian salt industry, it was established that the investment in machinery could even return a profit of approximately US$ 30,000 after the first five years of the program. As for fluoride costs, they are recoverable through a minimal increase in the price of salt. The investment from the public sector—to cover the costs of administration,

TABLE 6.1 Costs and benefits associated with caries prevention during a salt fluoridation program that lasts five years.

	PROGRAM YEAR					
	0	1	2	3	4	5
Discount rate[a]		0.893	0.797	0.712	0.636	0.567
Total Costs						
Fluoridation cost (in thousands of US$)b	265.6	109.8	99.5	96.7	118.9	94.4
Total Benefits						
Number of decayed teeth prevented (in millions)[c]	0	1.75	1.92	2.12	2.33	2.53
Saving in treatment (in millions of US$)[d]	0	5.25	5.76	6.36	6.99	7.69
Net saving (in millions US$)[e]	0	4.88[e]	5.66	6.26	6.87	6.75
Present value of the discounted saving (in millions of US$)	0	4.36	4.51	4.53	4.37	3.83

[a] This is calculated at the end of the year, at 12% annually.
[b] This includes front-end and operating costs.
[c] An initial preventive impact on 25% of the total population is assumed, from the second year of the program, with an annual additional reduction of 10% in the incidence of caries.
[d] A value of US$ 3 is assumed per decayed tooth avoided.
[e] It takes into account the cost of years 0 and 1.

monitoring, evaluation, and social marketing of the program—is approximately US$ 346,500 for the first six years of the program.

Results

This study's objective is to examine the economic feasibility of establishing a program for fluoridating salt for domestic use as a way to prevent caries in the short term. The methodology used has been to analyze the costs and expected benefits of the intervention over five years. From estimates obtained it follows that, to implement the program, the total cost to produce fluoridated salt to cover Bolivia's entire population during the five years of execution would be approximately US$ 785,000.

On the other hand, the benefit expected in the target population (which for purposes of the calculation is taken as 25% of the total population) would be the prevention of somewhat more than 10 million decayed teeth in the five years of the program. This represents a savings in the expenditure of curative dental health care of some US$ 32 million (estimating a cost of US$ 3 per dental visit of low complexity to a public sector clinic).

From the analysis, it can be concluded that the cost-benefit ratio would be 1:40. That is, for every US$ 1 invested in the program the country could potentially save US$ 40 by preventing a significant number of caries in the population. If the cost per consultation is estimated at US$ 10, the cost-benefit ratio would be 1:134. And if the cost of a dental visit is US$ 20, as occurs in private sector clinics, the cost-benefit ratio would increase to 1:268.

This analysis demonstrates a high return on investment for salt fluoridation. Due to variations according in social stratum and area of residency of population subgroups—especially in a heterogeneous society such as Bolivia's—the benefit is also going to have a differentiated effect. This means that a prevention program such as the one described will benefit to a greater degree those groups most affected by caries, namely, those at lower socioeconomic levels. In that respect, such a program embodies principles of equity and social justice, making it even more acceptable from a political standpoint.

With regard to the program's sustainability, the evaluation carried out indicates that the initial and operating costs are moderate. In Bolivia, the initial costs of the program could be discounted, by virtue of the fact that the mechanism for potential financing to provide salt plants with machinery and necessary technical capability, using the CREDISAL model, would permit those costs to be recovered in the short term and plants would even turn a profit of approximately US$ 30,000 at the end of six years. Furthermore, the plants' operating costs (personnel, inputs, maintenance) would be recoverable through a small rise in the price of salt.

If financial sustainability is understood as the capacity of the health system to generate and allocate sufficient resources to carry out planned activities and to maintain an acceptable level of coverage, it is highly likely that a salt fluoridation program can become self-sustaining in the short term. The necessary resources for its development and maintenance are reasonable. Thus, the aggregate cost is minimal, and the private sector is favorably disposed to provide technical and financing support.

This analysis is supported by favorable experiences with salt iodization programs, for which production costs have proved easily recoverable.

Thus, a program of salt fluoridation for domestic use constitutes a highly desirable intervention to control and reduce dental caries. The investment necessary to develop and maintain the program is moderate, and the benefits are significantly high, as has been demonstrated in several countries throughout the Region.

The cost-benefit study will review existing legislation related to the production and marketing of salt and to the addition of nutrients (such as in iodization) and, if necessary, will propose updating existing legislation. Points to be considered in updating or preparing salt fluoridation standards or legislation include:

- Specifications of fluoride content per kg of salt. This should be specified as a range rather than a set number. Sufficient flexibility has to be built in, as there is a possibilty that the range may have to be changed.
- Fluoride type to be utilized (potassium or sodium fluoride).
- Type of salt to be fluoridated. The salt distribution and consumption patterns need to be reviewed. This will enable good decisions to be

made as to what types of salt need to be fluoridated for such uses as bakeries, food production, and household use.

- Salt containers or packaging should bear legends or warnings about salt consumption.
- Recommended method for fluoridating salt. Legislation or regulations should incorporate the latest analytical techniques and should be able to be easily changed when these techniques advance or improve.
- Institution or agency that will monitor the program.
- Monitoring reports that salt plants should expect to submit.
- Analytical method for salt quality control.
- Sanctions for noncompliance with specifications for salt fluoridation.
- Issuing of a warning so that no other food or condiment is fluoridated.
- Issuing of a warning so that imported salt meets the specifications established for nationally produced salt.

Characteristics of the Salt Industry and the Market for Salt for Human Consumption

This study of the salt industry and salt sales and use should develop information on the following:

- Sources of salt and its production in small, mid-sized, and large plants.
- Current and projected demand for salt.
- The country's current salt supply.
- Geographic location of salt plants and distribution and marketing by the salt industry.
- Consumption of salt by the population.
- Critical supplies (acquisition of which presents challenges for the country's salt industry).
- Technology adopted by the industry (how salt is produced and iodized).
- The country's experience with salt iodization.
- The salt industry's role in fluoridation.

Technical Cooperation, Technological Transfer, and Available Resources for Developing a Salt Fluoridation Program

A salt fluoridation program to reduce the incidence and prevalence of caries requires financial and technical support from organizations interested in oral health. Table 6.2 classifies possible actors in such a

TABLE 6.2 Sources of cooperation for developing a national salt fluoridation program.

	Public	Private
Internal	Ministry of Health University	Rotary Club Private laboratories Lending institutions and banks Dental associations Foundations
External	World Bank IDB PAHO UNICEF Donor governments	Salt Institute (U.S.A.) Institute of Nutrition of Central America and Panama (INCAP)

project, as well as their private or public and local or international nature. Several alternatives exist for concerted support of the program. The government of each country is responsible for initiating necessary contacts with interested organizations to secure their involvement.

Initially, the institutions that could participate in a country should be identified, and then a complete investment proposal should be prepared for presentation to cooperation and financial agencies. Institutions committed to carrying out a salt fluoridation project should participate in preparing the proposal.

Apart from financial supporters, there are other public and private institutions that could assist with technical aspects of the project. These include institutions that can help with analysis of fluoride levels, as well as university laboratories and their researchers who can conduct baseline studies. Private lending institutions can provide assistance for funding technological development and could run credit programs for social development. They might be able to provide assistance in managing the technological development of salt fluoridation. The cooperation of dental associations can lend legitimacy and credibility to projects. Dentists, especially, play an important role in promoting salt fluoridation program as part of a comprehensive preventive effort; their support is critical to the program's success.

Baseline Studies

Salt fluoridation plans call for measurement of baseline oral health status. Two essential studies determine, (1) baseline information on dental caries and fluorosis and (2) baseline levels of fluoride in water supplies; PAHO recommends additional studies of (3) urinary fluoride excretion in children 3–5 years of age and (4) assessment of other available sources of fluoride.

PAHO developed standard protocols, but some countries have modified them to address specific research needs (*3*). Research protocols for all baseline studies are presented in Part 3.

Determining the Prevalence of Caries and Dental Fluorosis in Children 6–8 Years Old, and 12 and 15 Years Old

The purpose of this study is to establish a baseline of severity and prevalence of dental caries and fluorosis in children 6–8 years old, and 12 and 15 years of age. Baseline data allow comparisons to be made in future periodic assessments. These age groups are studied because at 6–8 years old one observes temporary dentition and the first permanent teeth; at 12 years of age, the first and second permanent molars can be examined; and at 15 years of age, erupted canines are observed. For the fluorosis study, only the upper teeth from canine to canine are taken into account.

These age groups should be studied simultaneously through a representative national sample taking into account that parts of the population may live in areas with varying levels of fluoride in drinking water, as well as the relationship between caries and dental fluorosis and existing fluoride concentrations in the water.

These studies are intended to assess the current situation and to predict the population's future oral health needs. In the event that there is no national or regional health authority with responsibility for determining oral health needs, then dental associations or university teaching institutions should conduct these studies periodically.

Determining Fluoride in Water Supplies

PAHO highly recommends that this important study be conducted. It is known that fluoride is present in various concentrations in water, depending on the water source, type of soil, depth of wells, and other environmental and seasonal factors. Each country must identify communities where the fluoride concentration is naturally high enough to prevent caries. Fluoridated salt should not be distributed in these communities to avoid the risk of dental fluorosis in children younger than 6 years old. This study should measure all drinking water sources, and should progressively become a periodic evaluation conducted every 4–5 years.

The main objective is to create a database of the country's community water supplies and categorize their fluoride concentration. In particular, the study should locate water supplies with fluoride concentrations above optimal levels, and identify the population served. Training seminars are recommended to coordinate study design, the recording of essential data, and the methodology for laboratory analysis using specific fluoride ion electronic meters.

Fluoride levels established for interpretation of data are low, moderate, optimal, and high:

Low concentration	0.00 to 0.39 parts per million (ppm)
Moderate concentration	0.40 to 0.69 ppm
Optimal concentration	0.70 to 1.49 ppm
High concentration	1.50 ppm and higher

Note: In warm climates, the minimum optimal concentration is 0.5 ppm, whereas in temperate and cold climates it is 0.7 ppm .

The study will be conducted following public and private sector sanitary guidelines for sampling drinking water in supply systems (described in Chapter 7, "Epidemiological Surveillance"). Samples from all sources and networks that supply water for human consumption will be collected to develop the national database.

Study results will indicate areas where fluoridated salt will be marketed and where there is a risk of fluorosis. Again, fluoridated salt should be consumed only in areas where fluoride concentrations are low or moderate. Areas with optimal and high fluoride concentrations will have to be monitored to prevent fluoridated salt from being sold there (*4*).

Determining Fluoride Excretion in Urine of Children 3–5 Years Old, Using 24-hour Samples

This study provides information on fluoride exposure, regardless of the source. It is used to determine whether children are receiving an adequate amount of fluoride to protect against dental caries, and to alert public health authorities if children are being exposed to undesirable amounts of fluoride that could cause unsightly dental fluorosis. After a salt fluoridation program is implemented, data collected from future studies will indicate whether children are being exposed to optimal amounts of fluoride, with minimum risk of dental fluorosis. The data are also used to advise the salt industry on possible adjustments of fluoride levels that might be needed. If strict quality control is exercised by the salt industry, regarding fluoride concentration in salt for human consumption, and if fluoride excretion rates are still above optimal levels, then other sources of fluoride exposure need to be investigated as possible causes of those excessive levels. Additional sources of fluoride that can raise the compound's concentration in humans include fluoride pills, tablets, lozenges, or drops, as well as some mineral waters and some black teas. Fluoride concentrations in populations that consume these products need to be studied.

The recommended methodology for performing these studies follows WHO guidelines. Twenty-four hours is the recommended monitoring period for time-controlled urine sampling. Essential data collected include volume, urinary collection period, fluoride concentration, and the age and weight of participating children. Fluoride concentration is determined using specific fluoride-ion electrodes and electronic meters. The information obtained is used to calculate the urinary fluoride excretion rate per hour and per 24-hours.

Monitoring of fluoride concentrations in urine is a convenient method for estimating ingestion of that ion in a given population. If in addition to concentration, the rate of urinary flow is determined, then the rate of excretion of fluoride through the urinary tract can be determined by multiplying the two factors. This procedure has the advantage of reducing the degree of variation between individuals, since every increase in the rate of flow tends to be related to a reduction in fluoride concentration in the urine, and vice versa. In addition, the urinary excretion rate reflects the fluoride level in blood plasma with adequate reliability (*5*).

This study will be conducted on a population sample of children 3–5 years old. Urine samples should be collected over 24 hours (estimates based on that method or on excretion rate are more reliable than those based on specific samples of urine). The samples will have to be representative of the total population of this age group, and of areas in the country with different fluoride levels in drinking water (*3*).

Fluoride excretion in urine will be reported in micrograms (μg) of fluoride per hour. This study will provide children's fluoride intake in relation to its excretion, before consumption of fluoridated salt begins (guidelines for the study of excretion of fluoride in urine are described in detail in Protocol 3, "Determining Urinary Fluoride Excretion in Children—Time-controlled Urine Sampling," in Chapter 10 of this book.)

Reference Data on Nutrition of Preschoolers

Nutritional surveillance provides information on the prevalence of malnutrition and its trends, potential nutritional problems, and the operation and effectiveness of nutritional interventions. This information facilitates decision-making by staff members responsible for public health programs, as well as formulation of strategies and planning and evaluation of programs.

Some countries have multisectoral food-and-nutrition surveillance systems located in the ministry of health or nutritional surveillance units within that ministry. Most countries have mechanisms for monitoring some nutritional indicators that make it possible to obtain information on preschool children (*6*).

At any age, an adequate supply of nutrients is necessary to maintain oral health. Early malnutrition affects tooth structure, delays eruption, and increases susceptibility to caries. It also is related to a greater risk of dental fluorosis (*8*).

Information on food consumption and the nutritional status of preschool children is vital for understanding the state of oral health and for determining the effect that the intake of natural fluoride through water or by consuming fluoridated salt can have. Information on food consumption and nutritional status can be obtained from national nutritional surveys or anthropometric studies.

In addition, it is necessary to conduct studies of fluoride content in the staple foods that are consumed most frequently by a country's population, in order to identify the principal sources of this element that are available to that population. Processed food that can be enriched with fluoride also should be identified, as should food of foreign origin, in case health measures must be taken to ban or limit its marketing (*3*).

Assessing other Fluoride Containing Products

This study collects information on other fluoride sources available to preschool children, in particular fluoride in toothpaste and in supplemental tablets, drops, or vitamins. It seeks parent or provider information about a child's use of toothpaste, age of initiation, frequency of use, brand of toothpaste, and supervision during toothbrushing. This study complements the study of urinary fluoride excretion.

Ingestion by children younger than 5 years of age of fluoridated toothpaste during toothbrushing (due to their inability to control the swallowing reflex) is of special interest, since the crowns of the permanent teeth are in the process of calcification and are susceptible to dental fluorosis. Many studies have demonstrated that ingestion of dentifrices during toothbrushing declines with age; children 5 years old were found to ingest between 26% and 35% of the total dentifrice used, while children 2–4 years old ingested approximately 35% (*8*).

Ingestion by children of significant quantities of fluoride in the form of toothpaste can put the child at risk of developing dental fluorosis. That risk increases if fluoride intake also increases through consumption of fluoridated salt.

It is therefore necessary to know the percentage of preschool children using fluoridated dentifrices and the fluoride concentrations in those products, and to provide information to health workers and parents, stressing the importance of supervising children's toothbrushing and of teaching children to use small quantities of paste and helping them to avoid swallowing it (*8*).

In addition, toothpaste manufacturers should be encouraged to produce products with lower fluoride concentrations for use by children; normally, these products have concentrations between 1,000 and 1,500 ppm fluoride, while children require 400–550 ppm for their brushing (*3*).

A growing number of pharmaceutical products containing organic or inorganic fluoride are used as fluoride supplements to prevent caries. It is thus necessary to determine what fluoridated products are marketed as supplements in a country, and which ones are regularly prescribed by health professionals (dentists, and pediatricians) without consideration of the natural fluoride levels in drinking water or the proper dosage for a patient's age and body weight.

It also is necessary to know the fluoride concentration in these supplements, with a view to limiting their sale when fluoridated salt is marketed in the country. The use of additional fluoride (such as through use of drops or tablets) by a population consuming fluoridated salt poses a risk of dental fluorosis (*3*).

General guidelines for carrying out these actions are described in Chapter 7, "Epidemiological Surveillance."

Determining Baseline Intake or Salt Consumption Per Person and Per Day

The population's salt consumption habits should be taken into account when determining how much fluoride will be added to salt for human consumption. If a great deal of salt is routinely eaten, then less fluoride should be added. If, on the contrary, salt consumption is minimal, the concentration of fluoride in salt will have to be greater (*9*).

It is recommended that information on the average salt intake by individuals in a population be obtained from the national nutrition institutes or programs, as well as from the salt industry. Only if such information is not available from those sources would a study of salt consumption, in a population sample that is representative of the country, have to be conducted (*10*).

As mentioned, information on salt consumption, along with other variables, enables determination of the dosage of fluoride to be added to salt to obtain a caries prophylactic effect.

Surveillance Systems and Quality Control

The purpose here is to establish criteria for epidemiological surveillance of caries and dental fluorosis related to the salt fluoridation program, as well as of conditions that can endanger the oral and overall health of the population. The guidelines will be established in accordance with results obtained from baseline studies and from monitoring of activities required by the program for its implementation. They will be applied in Phase II of the salt fluoridation program. (PAHO's recommendations for monitoring salt fluoridation programs can be found in Chapter 8 of this book.)

Determining the Dosage of Fluoride Ion per 1 kg of Salt

The initial dosage of fluoride ion will be determined in terms of information on the concentration of natural fluoride in drinking water, on the baseline for excretion of fluoride in urine, on intake or consumption of salt per person per day, on geochemical environmental aspects, and on certain behaviors that will increase the intake of additional fluoride, such as reboiling soups, thereby increasing the fluoride concentration, or an excessive consumption of some foods, such as tea.

The experiences of countries that already have implemented salt fluoridation programs also offer important lessons. The dosages they have applied are listed below (*11*):

- Switzerland, 250 mg F/1 kg salt
- France, 250 mg F/1 kg salt
- Jamaica, 250 mg F/1 kg salt
- Costa Rica, 200 mg F/1 kg salt
- Colombia, 200 mg F/1 kg salt
- Mexico, 250 mg F/1 kg salt
- Uruguay, 250 mg F/1 kg salt

Recommended dosage of fluoride is 200–250 mg/kg salt. It is sometimes more difficult to control the dosage with the wet method, which is usually used in plants with continuous production and high productivity.

PHASE II: FIRST EVALUATION

To reach this phase it is necessary to have obtained the information and conducted the baseline studies specified in Phase I, since those studies will be complemented by actions undertaken in Phase II.

Plant Equipment for the Production of Fluoridated Salt, by Production Method

- **Dry method.** Used in salt plants where there is batch production. In small-scale salt production, heavy mixing equipment with a capacity of 1–5 tons per hour is used for individual batches (*11*).
- **Wet method.** Used when the production process is continuous or done on a large scale. Intensive, high-speed, continuous mixing equipment is used (*4*).

Training of Personnel for the Program

In all countries, training will need to be provided in epidemiological monitoring of salt fluoridation programs. Every country should tailor its training to the type of surveillance that it will carry out, especially at intermediate and local levels. Training will be determined by the needs of each institution and sector participating and by the standards and legal provisions in force in each country.

It is recommended that training for health workers and salt-industry personnel that will participate in the implementation, dissemination, and evaluation of the salt fluoridation program be divided into two large areas:

- **Training for the work** is directed at the worker who will become an integral part of the program and will perform a function related to salt fluoridation. Its objective is to provide the individual with complete appropriate information about the activity that he or she will carry out. Training can be done with manuals for self-instruction or through formal courses.
- **Training in the work** consists of a systematized series of activities aimed at practice and in-service training to detect deficiencies or omissions in the execution of operations and provide advisory services.

Salt fluoridation programs should include a subprogram for personnel training, in which training needs are specified in accordance with the program's current phase. Some examples of training subjects are development and benefits of the salt fluoridation program; calibration in epidemiological oral health indexes; and analytical techniques to determine fluoride in water, salt, urine, and other materials.

Personnel to be trained include dentists, physicians, nurses, chemists, nutritionists, health monitors, administrative personnel, and health promoters, among others. Their training should be tailored to activities in which they are to participate. These activities should be carried out in coordination with health-education sections of each country's health institutions, as well as with universities (*4*).

Development of Monitoring Infrastructure

Laboratories may be provided with equipment (potentiometer, electrodes for fluoride, and an analytic balance), and with analysis material and reagents for the fluoride determinations. Likewise, laboratory staff may need training in techniques for determination of fluoride in water, salt, and urine. The number of laboratories that are set up should be in accordance with the degree of regionalization of each country's laboratory network, or with the regionalization that the country has established for epidemiological surveillance of salt fluoridation (*4*).

Mass Communication Strategy

At this point in the program, a strategy for mass communication should be developed and carried out for each population group. The portion of the population intended to receive fluoridated salt will be informed of its benefits. People living in areas where fluoride levels in drinking water exceed optimal concentrations should be warned against consuming fluoridated salt.

Additionally, information concerning restrictions on the use of systemic fluoride as a widespread preventive measure must be disseminated to health workers such as dentists, pediatricians, and gynecologists. The information disseminated should be simple, persuasive, understandable, and current.

Mass media and promotional materials should not encourage salt consumption, but only spread information on the benefit of consuming fluoridated salt in the usual quantity. At the same time, it is recommended that information on other activities that promote oral health (toothbrushing, use of dental floss after meals, adequate diet, and periodic visits to the dentist) be disseminated.

Mass communication media—radio, television, salt packaging, cooking magazines, posters, advertising material, pamphlets, or printed material on supermarket bags—should be selected according to the resources that are available (*12*).

Initiation of Epidemiological Surveillance

Epidemiological surveillance of the salt fluoridation program requires continual or periodic biological monitoring and chemical monitoring. The surveillance objective is to determine the caries prophylactic fluoride concentration in salt, in order to achieve maximum protection against caries with minimal risk of producing dental fluorosis, through indicators or conformance to standards (*3*).

Epidemiological surveillance includes the following chemical and biological monitoring activities, which must be completed in the program's Phase II (*13*).

Biological Monitoring

1. Monitoring of fluoride excretion in urine in children 3–5 years old, using 24-hour samples, beginning 15 months after having regularized the fluoride dosage in salt and after the population's consumption of fluoridated salt has begun.
2. Epidemiological survey of DMFT and dental fluorosis conducted seven years after implementation of the program in children 6–8 years old, 12 years old, and 15 years old.
3. Periodic monitoring of the nutritional status of preschoolers.

Biological monitoring must be repeated seven years after salt fluoridation begins, to determine the effectiveness and risks of the program. Results will highlight any corrective measures that should be undertaken to reach program objectives.

If there is evidence of higher than optimal fluoride concentrations in water in certain geographic areas, additional evaluations may be called for there.

Chemical Monitoring

1. Continuous monitoring of the fluoride concentration in drinking water.
2. Continuous monitoring of the marketing and use of other fluoride supplements, such as drops and tablets.

3. Periodic monitoring of the proper use of toothpaste by preschool children
4. Monitoring of other, newly introduced fluoride products.

Quality Control in the Production and Distribution of Fluoridated Salt

Quality control should be implemented by the health sector and by the salt industry from the start of fluoridated salt production (*4*).

1. **Quality control in the production process**—this monitoring is carried out by salt-plant personnel, who collect salt samples directly from the hoppers during the production process for analysis in the plant laboratory and any necessary correction of the fluoride dosage. Health sector personnel also visit salt plants to collect samples from the production line for analysis in health sector laboratories.
2. **Quality control in the distribution process**—marketing lines for salt and points of sale are monitored to confirm that the type of salt sold is appropriate for the area. Salt plants and health authorities should carry out this control. Monitoring of the marketing lines is done through monthly reports from the plant; monitoring to confirm the type of salt and fluoride dosage is done by collecting salt samples from the points of sale, with the samples analyzed in laboratories set up for monitoring the program.

Safety Aspects in the Production of Fluoridated Salt

Proper safety measures must be followed in the production process to reduce the risk of injury to personnel handling fluoride. The following safety measures should be followed:

- The exposure limit for potassium fluoride (KF) in terms of threshhold limit values (TLV) should be 2.5 mg of F per m^3 in eight hours, as recommended by the United Kingdom Health and Safety Executive and by the 1991–1992 United States American Conference of Government Industrial Hygienists (ACGIH).
- In handling the reagent, spills and the generation of powder should be avoided.
- Protective equipment worn by workers handling reagent should include:
  1. Unsupported Neoprene gloves (Neotop model) with diamond finish.
  2. Nonfogging chemical goggles.
  3. Masks for protection from powders and mists.
- First aid measures include:
  1. In case of ingestion or severe exposure of fluoride through inhalation, administer effervescent calcium gluconate tablets and copious amounts of water. Do not induce vomiting.
  2. In case of contact with the eyes, wash eyes immediately with copious amounts of water and continue irrigating with sterile saline solution.
  3. In case of contact with skin, wash contaminated area with copious amounts of water.

PHASE III: LONG-TERM EVALUATION AND CONSOLIDATION

This phase is characterized by established epidemiological surveillance and quality control in production and distribution (*13*). Procedures for these activities are identical to those called for during Phase II and are described in Chapter 7. These activities make it possible to confirm the fluoride dosage and evaluate the impact of salt fluoridation.

Epidemiological Surveillance Elements

- Continual verification of fluoride levels in drinking water.
- Survey of the DMFT index and dental fluorosis in children 6–8 years old, 12 years old, and 15 years old, conducted 14 years after implementation of the program.
- Periodic monitoring of excretion of fluoride in urine of children 3–5 years old, using 24-hour samples.

- Periodic monitoring of the nutritional status of preschool children.
- Periodic monitoring of the use of toothpaste by preschool children
- Continuous monitoring of marketing and use of other fluoride supplements, such as drops and tablets.

Quality Control in Production and Distribution

- At salt plants, regular monitoring to ensure the correct fluoride dosage.
- In the distribution of salt, monitoring to ensure that the type of salt and fluoride concentration are appropriate for the area where they are sold.

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7. EPIDEMIOLOGICAL SURVEILLANCE

The objective of conducting epidemiological surveillance of a national salt fluoridation program is to determine the proper dosage of fluoride in salt to achieve maximum protection against caries with minimum risk of producing dental fluorosis (*1*).

This section sets out general criteria for epidemiological surveillance of dental caries, periodontal disease, and dental fluorosis in the context of a salt fluoridation program.

GENERAL CONSIDERATIONS

To better understand this aspect of a salt fluoridation program, the following definitions are provided:

Epidemiology—the discipline of medicine that studies the natural historical processes of health and disease causes and distribution, as a collective process (*2*).

Epidemiological surveillance—the continuous, dynamic study of the state of health and of the factors that modify it, to determine changes occurring in the health of the population.

Monitoring—the periodic follow-up of the fundamental activities of a program, through the development of indicators or standards serving as variables that can be observed and measured (*3*).

Epidemiological Surveillance Requirements

Monitoring of a salt fluoridation program should be carried out by continuously and systematically collecting epidemiological information generated by dental services, laboratories, oral health surveys, and research in other areas and other community entities. This information is then processed, analyzed, interpreted, disseminated, and used as feedback about the program. Epidemiological surveillance requires:

Information—Chemical and biological monitoring generates data from surveys of DMFT indexes and dental fluorosis and from studies of excretion of fluoride in urine, of the concentration of fluoride in drinking water in different seasons, of fluoride content of salt, on the use of toothpaste by and the nutritional status of preschool children, and on marketing and use of fluoridated supplements (*4*).

Training—In implementing epidemiological surveillance, it will be the responsibility of each institution or sector (health, industrial, etc.) to carry out training at all required levels. Training may be necessary in analytical techniques for determining fluoride in water, salt, and urine, as well as in obtaining urine donors, collecting samples, and measuring epidemiological indicators.

Supervision and evaluation—Appropriate supervision and evaluation are needed to detect deviations, propose alternative solutions, and establish corrective measures by comparing obtained results with what has been programmed. These activities make it possible to determine the impact of salt fluoridation in caries reduction or in causing side effects like dental fluorosis.

Epidemiological Surveillance Measurements

Epidemiological surveillance of a salt fluoridation program measures pathologies, risk factors, and protective factors.

Those measurements are related to the monitoring of:

- Caries prevalence and incidence.
- Dental fluorosis prevalence and incidence.
- Fluoride concentration in salt.
- Levels of fluoride in drinking water in places where fluoridated salt is consumed.
- Restriction of the availability of fluoridated salt in areas where levels of fluoride in drinking water exceed predetermined concentrations.
- Fluoride concentration in products for oral hygiene (toothpastes, rinses).
- Use and concentration of fluoridated supplements (drops, tablets).
- Nutritional status of preschoolers.

Measures will be established, if necessary, in accordance with local, regional, and national epidemiological situations, and should meet official requirements that have been specified by those responsible for the salt fluoridation program or by health authorities. Examples include: restricting the use of fluoridated supplements (drops, tablets) through legislation; shutting down wells or water systems for human use that contain high levels of fluoride; and modifying specifications for producing fluoridated salt.

Organization of Epidemiological Surveillance

Epidemiological surveillance of a salt fluoridation program should be organized so that the information it generates is complete, accurate, and timely; so that it follows technical and administrative program specifications and those of other community entities; and so that it is in line with each country's geographic area. Surveillance organization extends from the operational (or local) level, on through state or provincial levels, and through the national level.

The organization of epidemiological surveillance should include the following structural elements:

Surveillance unit—At each technical and administrative level, any unit that conducts surveillance activities (including monitoring) will be considered a surveillance unit. The population in general, also is considered as a unit that is part of the program; it can informally report to the appropriate authorities and upper management levels on irregularities that it perceives in terms of salt use or its oral health. Every area of the technical and administrative levels that carries out surveillance activities (including monitoring) will be called a surveillance unit.

Institutional or interinstitutional groups—institutional groups are those in the areas of dentistry and epidemiology or the equivalent, trained by the institution that coordinates the program. Interinstitutional groups are those from other participating sectors, such as institutions responsible for water supply, trade associations, universities, and dental societies.

Standard-setting agencies—those responsible for the national salt fluoridation program in each country will represent the standard-setting agencies in conducting epidemiological surveillance at the different technical and administrative levels (*3*).

Planning and Monitoring

Without proper planning and monitoring, program results will be unreliable, no matter how much information is collected. Planning activities helps personnel know what they should do; monitoring makes it possible to quickly identify problems. Monitoring requires answering questions such as (*3*):

- What activities or tasks will be monitored?
- Who will monitor them and when?
- Where and how the monitoring will be carried out?

As a part of epidemiological surveillance, monitoring of salt fluoridation programs consists of activities carried out to determine the excretion of fluoride in human urine, concentrations of fluoride in water and in salt for human consumption, epidemiological oral health indexes, and other elements of interest to the program.

The basic activities of epidemiological surveillance are included in the biological and chemical monitoring described below (*4*).

BIOLOGICAL MONITORING

Biological monitoring enables periodic evaluation of the intake of fluoride and its impact on humans. As part of epidemiological surveillance of a salt fluoridation program, biological monitoring will be carried out among children 6–8, 12, and 15 years old to determine the DMFT index and the extent of dental fluorosis. Among children 3–5 years old, biological monitoring will be used to determine nutritional status and excretion of fluoride in urine. For analysis in urine, the potentiometric method with the specific fluoride electrode is to be used (based on the Nernst equation, which gives a simple relationship between the relative potential of an electrode and the concentration of the ionic species in solution). (See Table 7.1.)

Oral Health Surveys for Determining DMFT and Dental Fluorosis in Children 6–8, 12, and 15 Years Old

Oral health surveys are a fundamental part of Phase I (the feasibility assessment stage) of a salt fluoridation program to gauge the population's current situation and future oral health needs. Phase II (first evaluation) constitutes a core monitoring process for evaluation and control of the program's effectiveness and risks. In Phase III (consolidation and maintenance), epidemiological surveys provide the monitoring that allows determination of program effectiveness 14 years after implementation.

Studies to determine the state of oral health are the responsibility of authorities and administrators responsible for oral health services. If there is no national or regional dental health authority, then den-

TABLE 7.1 PAHO's recommendations for monitoring salt fluoridation programs.

Phase I Feasibility Assessment and Program Implementation	Phase II First Evaluation	Phase III Long-term Evaluation
Determination of fluoride water supplies	Periodic sampling and determination of fluoride in water supplies	Continued periodic sampling and determination of fluoride in water supplies
Nutritional/dietary survey in preschool children (possibly already available in some countries)	Nutritional/dietary surveys of preschool children	Nutritional/dietary surveys of preschool children
Baseline study of toothpaste use by preschool children	Periodic evaluation of toothpaste use by preschool children	Continued periodic evaluation of toothpaste use by preschool children
Baseline study of additional sources of fluoride intake (dietary supplements, fluoride-containing products)	Periodic monitoring of marketing of additional sources of fluoride intake	Periodic monitoring of marketing of additional sources of fluoride intake
Development of epidemiological surveillance guidelines for quality assurance and quality control of fluoridated salt	Periodic monitoring for quality assurance and control of fluoridated salt	Periodic monitoring for quality assurance and control of fluoridated salt
Baseline DMFT and dental fluorosis surveys in children 6–8, 12, and 15 years old	DMFT and dental fluorosis surveys in children 6–8, 12, and 15 years old, five to seven years after program implementation	DMFT and dental fluorosis surveys in children 6–8, 12, and 15 years old 14 years after program implementation
Initial assessment of urinary fluoride excretion in children 3–5 years old, one-sample/24 hours, after 15 months implementation of salt fluoridation in the market	Urinary fluoride excretion in children 3–5 years old, one sample/24 hours, 15 months after program implementation	Periodic evaluation of urinary fluoride excretion in children 3–5 years old (one sample/24 hours)

tal associations or teaching institutions should conduct periodic epidemiological surveys.

General Guidelines for Conducting the DMFT and Dental Fluorosis Survey

1. The national study of DMFT indexes and dental fluorosis will be carried out on a representative sample of children 6-8, 12, and 15 years old.
2. Determination of fluoride in water supplies should be conducted on a representative national sample, considering the different levels of fluoride in drinking water, in accordance with the following:
   - Low concentration, 0.00 to 0.39 ppm
   - Moderate concentration, 0.40 to 0.69 ppm
   - Optimal concentration, 0.70 to 1.49 ppm
   - High concentration, 1.50 ppm and above

   Note: In warm climates the established optimal minimum concentration is 0.5 ppm, whereas in temperate and cold climates, the figure is 0.7 ppm (as shown above).
3. Criteria for diagnosis and coding of the DMFT index will be those established by the World Health Organization in its publication on oral health surveys (*5*).
4. For the survey of dental fluorosis, the Dean Fluorosis Index will be used (*6*). Only the upper teeth, from canine to canine, will be assessed.
5. To maintain epidemiological surveillance of the salt fluoridation program, the baseline study of DMFT and dental fluorosis should be followed up by a second study five or seven years later.
6. The epidemiological survey should take into account the following aspects (*7*):
   a) Determination of the variable(s) to be sampled (such that later inferences about the population can be made with confidence). Variables may be:
   - Age (children 6–8, 12, and 15 years old, ages of interest to the program because of the chronology of tooth eruption).
   - Gender and socioeconomic level (factors influencing the oral health of children).
   - Total populations of the age groups selected for the country as a whole (used to calculate a representative sample).
   - Sample sizes and indexes. These will be calculated using children who attend school, which means that precise data on the numbers of children and schools throughout the entire country are required. This information should be requested from the national institution responsible for education. The number of children sampled should be balanced against the size of the population chosen in each province.
   - Fluoride level in water consumed by children chosen for sampling in different schools must be known. To this end, available data on fluoride concentration in drinking water will be matched with the areas chosen for determination of indexes; samples of drinking water supplied to areas where the schools are located will be collected for determination of fluoride levels.

   b) In light of the characteristics to be sampled and subsequently evaluated, the stratified random sampling method is recommended. This can be carried out on the basis of pilot studies conducted beforehand, by applying the formula for calculation of sample size; in this way, the samples are determined by stratum, for infinite or very large populations.

   c) For organizing the survey, the approval of school officials should be obtained; the programming and logistics of the survey should be established; emergency treatment for dental caries should be available to those examined; instruments, equipment, and necessary material should be obtained; the mechanism for sterilizing the instruments should be established; and sufficient quantity of survey sheets should be available.

   d) To assure reliability of results, criteria to be used by interviewers should be standardized (calibrated), a pilot exercise should be carried out, and 10% of the examinations should be replicated.

e) To conduct the survey, the following actions will be taken: establish contact with directors and teachers at the selected schools; organize participating personnel; prepare materials, instruments, and examination area; determine the epidemiological indexes.

f) Once sampling is completed, data are organized on the basis of age, gender, social stratum, fluoride level in water, DMFT index, and degree of dental fluorosis for each school surveyed in the different provinces.

g) For the analysis of the study data, the following statistical techniques are suggested:
   - Simple or multiple linear regressions (multivariate technique) with analysis of variance for the regression—useful in comparing correlations among the different factors taken into account in the stratified random sampling.
   - Discriminant analysis—a powerful multivariate study used to determine the relationship between the discriminating variable and the group of other variables of interest.

h) The final report of the survey will be prepared, enabling the scheduling of activities leading to the implementation of salt fluoridation programs or providing feedback for existing ones.

Determining Fluoride Excretion in Urine in Children 3–5 Years Old

The process of fluoride excretion involves a number of variable characteristics of renal function, among them the rate of glomerular filtration, the rate of urinary flow, and the pH of the urine (the average rate of excretion of fluoride increases with alkalinity).

The actual percentage of absorbed fluoride that is excreted varies in accordance with an individual's history of exposure to fluoride and with age, since both influence the effectiveness of the skeletal component of the hemostatic mechanism; however, other factors also intervene, especially the concentration of ingested fluoride and fluid intake.

Young children excrete a lower percentage of ingested fluorides than adults, which is attributed to the higher rate of fixation of these compounds in children's bones and other calcified tissues. Data on children under 6 are limited, but in general they probably excrete 20%–30% of ingested fluoride in their urine, whereas adults excrete 50%–60%.

Fluoride concentration in plasma and in urine tends to be very similar. As a result, fluoride levels are good indicators of recent fluoride intake (8).

Results obtained from determination of fluoride excretion in urine make it possible to calculate and evaluate the population's daily total fluoride intake, in accordance with the level of fluoride that each vehicle contains. If data from a program assessing fluoride intake are expressed in terms of excretion rate, it is important to determine when in the day samples should be collected from the subjects. This is due to the fact that such a program should estimate the daily fluoride intake based on the daily fluoride excretion in the urine. To solve this problem, it is recommended that a salt fluoridation program design studies using 24-hour urine collections over an appropriate period of time.

Urinary flow rate is determined from the volume of urine collected and the time elapsed between the first emptying of the bladder and the second—an approach that has the following advantages:

1. It reduces the degree of variation from one person to another, since as the urinary flow rate increases, the concentration of fluoride in the urine decreases, and vice versa.
2. The urinary excretion rate also reflects the fluoride level in blood plasma with sufficient reliability.
3. For adults who consume salt fluoridated at 250 ppm, average urinary excretion for 24 hours depends on the quantities of fluoridated salt consumed, according to Wespi and Burgi.
4. Using the rate of excretion, the dynamics of excretion can be analyzed; for example, the fluoride peak that forms after meals can be evaluated.

It is important to recall that children with growing bone systems take more time to regularize their fluoride metabolism so that urinary excretion is adjusted to the increase in fluoride ingestion, since this is an element that the bones seek. The amount of fluoride in children depends on their current growth period (*9*).

In light of the above, the following guidelines should be considered for monitoring fluoride excretion in urine of children 3–5 years old.

General Guidelines for Monitoring Fluoride Excretion in Urine

1. Fluoride excretion in urine in children 3–5 years old should be studied first in the feasibility or initiation phase of a salt fluoridation program, to establish a baseline before fluoridated salt is marketed.
2. In the program's second phase, 15 months after implementing the measurement and control of the marketing and consumption of fluoridated salt, monitoring of fluoride excretion in urine in children 3–5 years old should be initiated. Moreover, monitoring of fluoride excretion in urine should be carried out periodically (every 12 months) during the second and third phases of the salt fluoridation program.
3. Studies should be carried out in a population sample of 180 children 3–5 years old who live in areas with different altitudes, climates, and levels of fluoride in the drinking water.
4. Twenty-four-hour samples should be collected, with supervision of every donor on at least two occasions.
5. Selected donors should have resided in the area a minimum of six months.
6. Children not ingesting any drugs (including vitamins) should be selected as urine donors.
7. Monitoring personnel should be supervised during the following phases: donor selection; sampling; sample conservation and transfer to laboratories; and sample processing at laboratories.
8. Children's urine samples should be collected in 1,000 ml, wide-mouth plastic or polyethylene containers with double caps.
9. If samples will not be analyzed within the first few hours after collection, a preservative that does not interfere with the chemical reaction in the analysis, such as thymol, should be added to the container prior to collection.
10. Urine samples should be kept refrigerated at 7°–14°C until laboratory analysis, with a maximum storage time of 15 days.
11. Samples should be analyzed individually, to allow comparison of the variation among individuals with regard to fluoride excretion and, presumably, fluoride intake.
12. Excretion of fluoride in urine should be determined using a potentiometer with fluoride ion-specific and reference electrodes, or else with a combination electrode, giving results in µg/hour.
13. Internal and external quality control should be carried out at laboratories responsible for the analyses:
    - Each laboratory will periodically carry out internal quality control, and the information should be at the disposal of supervisory personnel.
    - Those responsible for the salt fluoridation program and national laboratory personnel will conduct external quality control.
14. Dental and nursing personnel should be responsible for taking urine samples. Other trained health workers can participate, if necessary.
15. A form should be filled out and numbered progressively for each child donor, and the collected urine sample should be marked with the same number (*1*).

The pH values and flow rates of monitoring subjects should be determined, because these variables can influence both the concentration and rate of fluoride excretion. Dietary differences make it probable that the concentrations and the excretion rates are greater than in other populations and that the average pH will be relatively high. If the rate of urinary flow is relatively high, then fluoride concentrations will be lower and the excretion rates somewhat greater than in other populations, and vice versa. In accordance with the fluoride, pH, and urinary flow results, adjustments could be required in the fluoride dosage in salt.

Procedures for Biological Monitoring of 24 Hours of Fluoride Excretion in Urine in Children 3–5 Years Old

1. A training course covering urine collection and sample conservation and shipment should be conducted for personnel who will participate in the study.
2. Study personnel should be informed of areas to be monitored and told to keep in mind the different ranges of fluoride levels in drinking water and the number of samples to be collected in each place.
3. Homes or institutions should be visited to recruit urine donors.
4. Parents or others responsible for participating children should be informed of the study's objective and the procedure for collecting urine samples. A signed consent form should be obtained from the parent or responsible adult.
5. At each donor residence a numbered identification form should be filled out and the containers (labeled with the same identification number) to be used for urine collection should be left at the residence.
6. The parents or others responsible for the children in the study should be instructed to discard the first urine excreted by the child upon awakening in the morning and to record the hour when that first urination occurs; this first-urination hour marks the starting time of the 24-hour period during which the urine sample is collected.
7. Study participants should be told to collect all the urine excreted in each urination during the rest of the day and night, and also the first urine excreted the following morning. Parents or others responsible for the child should be asked to also record the hour that the first urine of the morning of the following day is issued, indicating that at point the collection of the urine sample is finished.
8. Urine from female donors should be collected in chamber pots or wide containers, which should be plastic, after which all the urine should be poured into the plastic bottle provided for collection.
9. Urine donors should be instructed to close urine containers airtight and keep them in a cool place.
10. Health workers should collect urine samples the day after collection begins and should confirm that urine-sample identification forms have been filled out correctly.
11. Urine samples and identification forms should be sent to the laboratory where they will be analyzed.

Monitoring the Nutritional Status of Preschool Children

In Phase I (feasibility assessment) of the salt fluoridation program, baseline data on the nutritional status of preschool children should be obtained. Continuous monitoring of nutrition in this population group is carried out in Phase II (first evaluation) and Phase III (consolidation and maintenance).

In many developing countries, malnutrition affects children most during the first years of life, when growth is rapid and nutritional needs are higher and more specific. Thus, when poverty limits availability of food, children suffer most. When children's food does not meet their energy requirements, their rate of growth is restricted and their health compromised. Hence, when one wants to know a community's nutritional status, the status of children up 6 years old is used as an indicator, because the effects of malnutrition are more noticeable in this age group (*10*).

For the purposes of a salt fluoridation program, monitoring the nutritional status of preschool children is especially important, since in children under 5 years of age one begins to observe some nutrition-related alterations (caries, fluorosis, etc.) in the teeth. This monitoring will provide information on the prevalence of malnutrition and its trends, on potential problems for oral health, and on the feasibility and effectiveness of the salt fluoridation intervention.

Because most dentists or coordinators of salt fluoridation programs may have limited experience in evaluating data on nutrition, it is necessary to coordinate the monitoring effort with food and nutrition institutions. In many countries, food and nutrition surveillance systems will already have been set up to select, compile, process, analyze, and interpret data from existing sources of information (*10*).

In the context of salt fluoridation, each country should establish and test its own procedures for monitoring the nutritional status of preschool children, always using a minimum of common and safe indicators related to the availability, consumption, and biological utilization of food. Methods for obtaining the information could include:

- **Study of anthropometric measurements in a population sample.** In this study, the nutritional status of children is evaluated using weight, height, chest circumference, and triceps skin fold from a sample of children 3–5 years old.
- **Dietary survey in a population sample.** This survey will collect data obtained through consultation or questioning, including data on children's food consumption, expressed in terms of nutrients.

The fluoride content of natural or processed foods that are consumed regularly by the population will be determined. In addition, there should be periodic inspection of imported processed food whose content specifies that it has been enriched or fortified with fluoride; this includes foods suspected of containing fluoride because of water they contain or their place of origin.

For quantification of fluoride in food, the following procedures are recommended:

1. Foods consumed most frequently should be grouped according to United Nations Food and Agriculture Organization classification—for example, seeds, vegetables, grains, and teas.
2. For selecting food samples, the country's geoeconomic regions should be taken into account—a single region can be included in or can cover an entire province, but one province can also contain several regions—as should the various nutritional areas.
3. Once the food groups are identified, samples should be collected and analyzed in the laboratory, within 24 hours in the case of perishable food.

The following two techniques are recommended for determining fluoride in food:

Method 1

This method is based on separating the fluoride from a dry or fresh food sample through diffusion of the hydrofluoric acid formed. The fluoride measurement is carried out using an ion-specific electrode.

Equipment and Materials:

- Potentiometer/ion analyzer
- Analytic balance precise to 0.0001 g
- Fluoride ion-specific and reference electrodes
- Polyethylene petri dish
- Volumetric flasks, 100 ml
- Pipettes
- Convection oven
- Magnetic stirrer

Reagents:

- Sodium fluoride.
- Perchloric acid, 40%.
- Silver sulfate.
- Sodium hydroxide.
- Glacial acetic acid.
- Sodium chloride.
- A total ionic strength adjuster buffer (TISAB).

Operating Procedure. To prepare the sample, liquefy, dry, and grind the food. In the cover of the petri dish, place 0.1 ml of 0.5 M NaOH in the form of drops (25 to 30 drops) and dry in an oven at 50°C. In the petri dish, weigh 0.1 g of the food and add 0.3 g of silver sulfate and 2 ml of perchloric acid.

Immediately cover the dish with its lid. Agitate gently and place the covered petri dish in an oven at 45°–50°C for 20 hours. At the end of that time, remove the cover of the petri dish and add 2 ml of TISAB; agitate using a small magnetic stirrer to mix the sample, then read it in the ion analyzer.

To prepare the calibration curve, using pipettes, put 0.1 ml of each work standard (0.00, 0.05, 0.1, 0.5, 1.0, 5.0, 10.0, 50.0, and 100.0 μg/ml fluoride) in petri dishes; add silver sulfate and perchloric acid to each of them in the same quantities as for the sample. Follow the same procedure as was used in the sample.

Obtaining Results. The fluoride content in the food sample is determined by interpolation, using the calibration curve. On semilogarithmic paper, millivolts are graphed against the logarithm of the standard fluoride concentration, yielding a straight line. Use the equation of the straight line and the millivolts obtained with the sample to determine the fluoride concentration in µg/ml.

Method 2

This method of fluoride analysis is based on ash production.

Samples are washed thoroughly with deionized water and broken up with an agate mortar and pestle. They are dried for three hours at 110°C; 20 g of each sample are taken and mixed thoroughly with one g of calcium oxide in nickel vessels. The pH is measured and the samples are dried completely on a hot plate, at which point they will be in a solid state. To produce the ash, the samples are placed in an oven at 500°C for 24 hours.

In the case of tea processing, aliquots of 20 ml are obtained at 0, 3, 5, 10, 15, and 30 minutes of infusion. To prepare the infusions, 2.5 g of tea are added to 250 ml of deionized water (*11*).

Analysis Method. To determine the fluoride content of each sample, an ion-specific electrode is used, following calibration based on comparison with results from fluoride solutions of 0.0, 0.1, 0.5, 1.0, and 5.0 ppm. These solutions are prepared from a standard fluoride solution and are diluted with TISAB.

CHEMICAL MONITORING

Chemical monitoring is a technical procedure that detects the presence of a chemical element (in this case, fluoride) in a substance such as water or salt, without altering the chemical element.

For fluoride analysis in chemical monitoring, the potentiometer method is used (based on the Nernst equation, which gives a simple relationship between the relative potential of an electrode and the concentration of the ionic species in the solution).

In epidemiological surveillance of a salt fluoridation program, chemical monitoring is carried out periodically to detect and quantify fluoride in water and salt, as described below.

Determining Fluoride in Drinking Water—Wells and Water Supply Networks

Periodic chemical monitoring of fluoride concentration in drinking water permits inferences to be made regarding the population's daily intake of natural fluoride. Epidemiological studies have demonstrated that there is a relationship between the concentration of natural fluoride in water and levels of dental fluorosis and the prevalence and severity of caries. Thus, results of water monitoring should be used as feedback to the salt fluoridation program, to control the marketing of fluoridated salt, and to establish the necessary surveillance in places where the population is at risk of dental fluorosis.

Where fluoride levels in drinking water are high, institutions responsible for water supply should be urged to consider mixing well water that has high fluoride levels with water with low fluoride levels. Defluoridation of water may soon be another possible solution to high fluoride levels in well water. In any case, it is the responsibility of health workers to inform the public of measures it can take to reduce the harmful effects of this element (*1*).

Monitoring the fluoride concentration in drinking water should be carried out in accordance with the following guidelines (*1*).

1. Because the fluoride concentration in aquifers can vary, monitoring of the concentration of natural fluoride in drinking water should be carried out at least twice a year in different seasons (rainy and dry).
2. To facilitate monitoring of fluoride concentration in drinking water, populations will be classified according to whether there are more than 10,000 inhabitants or fewer; depending on the country's total population and its geographic distribution, classification based on 5,000 inhabitants may be appropriate.

3. A national catalog of drinking water sources will be prepared; because water supply systems may be opened or closed over time, information on the number and location of wells and water supply networks should be updated every six months.
4. Water samples will be taken from sources used for human consumption—the water supply system, storage tanks, pumping stations, supply and distribution lines of the delivery system, wells, and springs.
5. For water sample collection, 125 to 200 ml plastic receptacles will be used, with covers of the same material that can be hermetically sealed.
6. All water samples collected should be labeled and an identification form should be filled out for each.
7. The potentiometer method with an ion-specific electrode should be used for the fluoride analysis. The colorimetric method is not recommended because it lacks precision.
8. Fluoride concentration in water will be given in parts per million (ppm) and will be classified according to the following:
   - Low concentration, 0.00 to 0.39 ppm
   - Moderate concentration, 0.40 to 0.69 ppm
   - Optimal concentration, 0.70 to 1.49 ppm
   - High concentration, 1.50 ppm and above

   Note: For warm climates, the established minimum optimal concentration is 0.5 ppm; for temperate and cold climates, it is 0.7 ppm (as shown above).
9. Laboratories should send results of analyses to those responsible for the epidemiological surveillance of the program.

Materials

To collect samples for monitoring fluoride in water the following materials are necessary:

- Plastic containers (125 to 200 ml) with covers of the same material that provide airtight sealing
- Containers or boxes for transferring samples
- Self-adhesive labels
- Ball-point pens (indelible ink)
- Forms for sample identification and for shipment to the laboratory

Sampling the Supply System

1. Open the system valve and allow the water to run for approximately one minute.
2. Before taking the sample, rinse the container two or three times with the running water.
3. Take the water sample (fill bottle with water) and put the airtight cover in place.

Sampling Bodies of Surface Water, Storage Tanks, Wells, or Springs

1. Uncover the sample container and submerge it in the water with the neck downwards to a depth of 20 cm to 30 cm. In all cases, avoid taking the sample from the surface or from a depth greater than 30 cm.
2. When it is not possible to take the sample by extending the arm, tie a weight to the sample container using a clean thread. Lower the container into the well, unrolling the thread slowly. When the sample has been collected, raise the container and put the airtight cover in place.

Labeling Sample Containers

1. Prepare a report form with date of collection, registration number, sample identification.
2. Write identification data on the labels in indelible ink.
3. Affix a label to the container and note a registration number with date, and identify the sample.
4. Fill out a form and verify information for fluoride ion in water to provide complementary data that cannot be noted on the sample container.

Handling the Sample

- Place the labeled samples in a box or container that will not be damaged by the weight.
- Keep water samples cool until they are received by the laboratory.

Control of the Samples

- Deliver samples with their corresponding forms to the laboratory.
- Keep a list of the samples delivered.

Chemical Analysis of the Samples

- Use the potentiometer method to analyze the water samples.
- Store samples for no more than 15 days before delivering to the laboratory.
- Analyze the samples and fill out the section of the form that corresponds to the laboratory for each sample.
- Record results in parts per million (ppm).
- Send results to those responsible for the program's epidemiological surveillance.

Determining Fluoride in Water Supplies

To determine fluoride in water the potentiometer method (which is based on the Nernst equation) should be used (*11*).

Equipment and Materials

- Potentiometer/ion analyzer
- Fluoride ion-specific electrodes
- Reference electrodes
- Thermometer, 0.00 to 50°C
- Magnetic stirrer
- Analytic balance precise to 0.0001 g
- Nalgene material (plastic)
- Volumetric flasks, 100 ml and 1,000 ml
- Volumetric pipettes, 1, 2, 3, 5, 10, 25, and 50 ml

Reagents

- Distilled water
- Glacial acetic acid
- Sodium citrate
- Sodium hydroxide
- Sodium chloride
- Sodium fluoride
- Hydrochloric acid, 37%
- Tris (hydroxymethyl) amino methane
- Sodium tartrate
- TISAB

Preparation of TISAB

Low-level TISAB. To a 1,000 ml precipitation flask, add 500 ml of distilled water, 57 ml of glacial acetic acid, and 58 g of sodium chloride. Stir the mixture until the salt is completely dissolved and allow to cool. The pH electrode is introduced into the solution and 5 M NaOH sodium hydroxide is added gradually, until the pH is between 5.0 and 5.5. The cooled solution is poured into a volumetric flask, and distilled water is added to bring it up to the ¾ volume.

TISAB IV (when water contains large quantities of iron or aluminum). To approximately 500 ml of distilled water, add 84 ml of concentrated hydrochloric acid (36% to 38%), 242 g of tris (hydroxymethyl) amino methane, and 230 g of sodium tartrate. Agitate until the solid is dissolved and allow to cool to room temperature. Transfer to a 1,000 ml volumetric flask and dilute just below the 1,000 ml mark with distilled water.

Preparation of the Standard Curve

Prepare a standard solution at 1,000 ppm using fluoride of known purity. Working standards are prepared by successive dilution and may have the following concentrations: 0.1, 0.3, 0.5, 1.0, 1.5, and 2.0 ppm. The same volume of TISAB should be added to all the standards (maintaining a 1:1 ratio between the standard volumes and TISAB).

Measurement of Fluoride Ion

An aliquot of 25 ml of water is added to an empty plastic precipitation flask, to which is added an equal volume of TISAB. The resulting mixture is agitated using a magnetic stirrer; the electrodes are introduced; and after three minutes the reading is taken in millivolts. Before reading the samples, the electrodes are conditioned, and the (working) standard curve is read. The fluoride concentration in the sample is determined by interpolation using the calibration curve (fluoride standards of 0.1, 0.3, 0.5, 1.0, 1.5, and 2.0 ppm).

When direct-reading potentiometers are utilized, fluoride concentration in ppm is obtained directly.

MONITORING FLUORIDE CONCENTRATION IN SALT AND IN THE DISTRIBUTION NETWORK

Another aspect of chemical monitoring involves the concentration of fluoride in salt; once fluoridation is initiated, quality assurance consists of controlling the dosage of the product.

This monitoring will make it possible to know whether fluoridated salt that is being produced and marketed complies with legislative provisions, and ensures that the population consumes salt with the adequate fluoride dosage—one that prevents caries without risk of dental fluorosis.

Monitoring of fluoride concentration in salt is established at the time that the production of fluoridated salt begins, and monitoring should continue throughout the duration of the salt fluoridation program (*1*, *12*).

Quality Control in the Salt Plant's Production Process

(a) For control of reagent dosage, the operator will be responsible for taking a sample every two hours from what drops from the helicoids conveyor, in order to analyze it and take corrective actions if necessary. In a small-scale salt plant, the sample will be taken from the hoppers after mixing, and will be analyzed so that corrective measures can be taken.

(b) The fluoride content in samples that are analyzed in the laboratory will be certified, and a daily report issued and made available to health authorities.

(c) For the analytical determination of fluoride, the potentiometer method will be utilized, with ion-specific and reference electrodes, or a combination electrode.

(d) It is suggested that a computer program (quality-alert software) be used to help manage monitoring, enabling data to be processed daily and a report generated monthly for industry and health authorities.

The leading indicators for monitoring the production process are the following:

X, arithmetic mean
R, range
O, standard deviation
CPI, process control constant

Quality control in the production process by health authorities

(a) Prepare and update a catalog of all salt-producing plants that participate in the program.

(b) Develop a schedule so that health authorities can obtain samples from all plants and certify equipment and facilities.

(c) Collect salt samples in plants during the production process.

(d) Analyze salt samples in laboratories involved in monitoring the salt fluoridation program.

(e) Report results of monitoring and any observations to the plants, indicating any sanctions, if warranted.

(f) Collect and analyze, from time to time, samples from salt packages that weigh over 20 kg and that are transported in vehicles for prolonged periods of time over long distances; this is done to verify the homogeneous distribution of fluoride in the salt, or its separation, produced by vibration from the moving vehicle.

Quality Control of the Plant's Distribution

(a) All deliveries will be controlled for type of product and brand name, to ensure that the type of salt corresponds to the area where it is intended to be marketed

(b) With regard to transportation of salt, the shipper should present copies of shipping invoices and the shipping manifest, showing the original stamps that indicate receipt of the product by the clients in question; this ensures that each type of salt is delivered to the point of sale where it should be consumed.

Quality Control of Distribution by Health Authorities

(a) Once fluoridated salt leaves the salt plant for warehouses and points of sale, the end product (bag or box) should be sampled to determine the fluoride content, and to compare it with the concentration established by the fluoridation program in the country.

(b) An annual schedule for sampling salt at points of sale and storage sites should be set up. The frequency of sampling should be dictated by the schedule of deliveries from salt plants or by the infrastructure of the laboratories.

(c) Salt sampling should be conducted by health inspectors, personnel responsible for the salt fluoridation program, or staff trained for this purpose.

(d) Sampling will be carried out in areas where fluoridated salt is sold, as well as where its sale is prohibited, in order to confirm appropriate marketing.

(e) The collected information should be recorded in a format specified for this activity.

(f) Closed salt packages will be obtained for sampling. When the required sample is fewer than five packages (1-kg bags or boxes), the municipality, community, or locality (area) should be selected at random.

(g) When the sample consists of five packages (1-kg bags or boxes) or more, and more than one municipality (area) is involved, the sampling should be distributed proportionately; the communities or localities within the municipality should be selected at random.

(h) The results obtained should be sent to the appropriate health authories in order to comply with each country's health requirements, regulations, or official standards for fluoridated salt.

(i) Safety measures should be applied when it is detected that the establishment where fluoridated salt is marketed or distributed does not meet the minimum sanitary standards or if it is confirmed or suspected that the product does not meet the requirements or could be harmful to the population, safety measures should be applied.

MONITORING FLUORIDATED SALT IN PLANTS, WAREHOUSES, AND POINTS OF SALE

Sampling in the Plant by Health Workers

(a) A salt sample will be taken every hour until at least five samples have been collected directly from the hoppers or from material that falls from the helicoid conveyor during production. Each sample will be divided into three equal parts, and each part placed in a plastic bag.

(b) Each sample (minimum 5g) will be identified as to:

- the type of salt (with fluoride or without fluoride),
- lot number, and
- date.

(c) One of the samples will be delivered to the salt plant to be analyzed in its laboratory; the other sample will be sealed and kept as a control for any clarification that may be necessary; the third sample will be analyzed in the health sector laboratory.

Sampling at Points of Sale and Warehouses by Health Workers

(a) A minimum of five samples, selected randomly, will be collected per lot. Each sample will be completely collected in its original packaging (bag or box).

(b)

- A label will be affixed to the original packaging, so as not to cover important product data.
- On that label, the identification of the sample number and date of sampling should be noted.
- A form should be filled out for shipping samples to the laboratory. The labeled samples are placed in a plastic container for transfer to the laboratory.

Analysis of the Samples

- Samples will be delivered to the laboratory with their corresponding forms, including a list of the samples being delivered.
- Samples should be stored for no longer than 15 days.
- For analyzing the fluoride concentration in salt, the potentiometer method (with fluoride ion-specific and reference electrodes) will be used.

- Results will be sent to those responsible for the salt fluoridation program or forwarded for epidemiological surveillance.
- The salt plants, warehouses, or points of sale where samples were collected will be notified of sampling results.

Fluoride Determination in Salt

The ion-specific electrode technique is used to determine fluoride in salt for human consumption.

Equipment and Materials

- pH meter and ion analyzer
- Fluoride ion-specific and reference electrodes
- Water bath
- Thermometer, 0.00 to 50°C
- Magnetic stirrer
- Analytic balance precise to 0.1 mg
- Nalgene material (plastic)
- Precipitation flasks, 100 ml and 1,000 ml
- Volumetric pipettes, 1, 2, 3, 5, 10, 25, and 50 ml

Reagents

- Distilled water
- Glacial acetic acid
- Sodium chloride
- Sodium citrate
- Sodium fluoride
- Sodium hydroxide
- TISAB

Preparation

Into a 1,000 ml precipitation flask, pour 500 ml of distilled water and add 57 ml of glacial acetic acid, 58 g of sodium chloride, and 12 g of sodium citrate. Stir the mixture until the solids are completely dissolved, then allow to cool.

Introduce the pH meter electrode in the solution and add 5 M sodium hydroxide (NaOH) until the pH is between 5.0 and 5.5. Once cooled, pour the solution into a 1,000 ml volumetric flask and add distilled water to bring the liquid level up to the 1,000 ml mark. The solution is stored in a cool dark place.

Preparation of the Calibration Curve

Prepare a standard solution at 1,000 ppm, using sodium fluoride of known purity. By successive dilution, standard solutions with the following concentrations are prepared: 1, 3, 5, 8, and 10 ppm. The calibration curve should be constructed using at least five points. To all the standards an equal volume of TISAB should be added.

MONITORING THE MARKETING AND USE OF FLUORIDATED SUPPLEMENTS (DROPS AND TABLETS)

The study of systemic fluorides already on the market, such as drops or tablets, and the frequency with which the population uses them, should be carried before production of fluoridated salt begins. Periodic monitoring should continue as long as these supplements are marketed; precautionary measures may be called for, such as withdrawal of these products from the market or restriction of their availability by requiring medical prescription.

Although systemic fluorides should be used by in all countries and regions as a public health measure to reduce the prevalence of caries, each country or region should use only one such measure, to prevent excessive fluoride ingestion. For example, as stated previously, fluoridated salt should not be distributed in communities whose water has sufficient fluoride concentrations. Nor should fluoridated supplements, such as drops and tablets, be used where fluoridated salt is already consumed, because it poses a risk of dental fluorosis.

In Phase I of a salt fluoridation program (feasibility assessment), a baseline study of the marketing and use of fluoridated supplements will be conducted. In Phase II (first evaluation) and Phase III (consolidation and maintenance), continuous monitoring will be carried out as part of the epidemiological surveillance that the program requires.

In order to monitor the fluoridated supplements, do the following:

1. Collect the names and specifications of fluoride supplements on the market and the names of

their manufacturers. This information can be obtained through institutions responsible for registering supplies and drugs in the health sector.

2. Eliminate fluorides for systemic use from lists of basic drugs used by institutions providing health services.
3. Develop a proposal to enact legislation, so that additional sources of fluoride intake are banned, such as fluoridated supplements, drops and tablets.
4. Establish protocols for health authorities to verify if fluoride products are being produced. If fluoride products are available, health authorities should test product samples from points of sale to verify their quality and determine in the appropriate laboratories the fluoride content of supplements (drops and tablets).
5. Prepare a program to inform health professionals (dentists, physicians, etc.) about the requirement that fluorides for systemic use only be available by prescription.

MONITORING THE USE OF FLUORIDATED TOOTHPASTE IN PRESCHOOL CHILDREN

As mentioned previously, children under 5 ingest significant quantities of fluoride when using fluoridated toothpastes. Depending on the frequency of brushing and the quantity ingested, children can be at risk of developing dental fluorosis, since the quantity of fluoride in ingested toothpaste is close to three times that from dietary sources (*13*). It should be stressed here how important it is for dental professionals to become involved at the very beginning of salt fluoridation projects. Dentists must be well informed about the advantages of using low-fluoride toothpastes. Furthermore, such toothpastes are generally desirable, whether or not systemic fluoride is administered through salt or water or not at all.

Thus, it is necessary to conduct a baseline study in Phase I of a salt fluoridation program and to carry out periodic monitoring during Phases II and III to determine the number of preschool children using fluoridated toothpastes and the fluoride concentration in those products, with a view to implementing actions by health workers and parents to promote oral health. Stress should be placed on the importance of supervising children's toothbrushing, instructing them to use small quantities of paste, and of teaching them to avoid swallowing it.

General guidelines for monitoring toothpaste use by preschool children include:

1. Identify all toothpastes in the market and their fluoride concentrations; this information can be obtained from chambers of commerce. To confirm the fluoride concentration of toothpases, samples should be collected for laboratory analysis.
2. In a population sample of mothers and preschool children, periodically program the use of directed interviews and/or questionnaires on toothpaste use and frequency of brushing by children.
3. Encourage the plants that manufacture oral hygiene products to produce children's toothpastes with fluoride concentrations from 250 to 500 ppm.
4. Prepare a mass communication program on the proper use of fluoridated toothpaste by children under 5.

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Dust of the sea,
in you the tongue receives
a kiss from ocean night:
taste imparts to every seasoned
dish your ocean essence;
the smallest, miniature
wave from the saltcellar
reveals to us
more than domestic whiteness;
in it, we taste infinitude.

Pablo Neruda, excerpt from "Ode to Salt"

Tool-kit for Decision-makers, Health Planners, Legislators, Epidemiologists, and Health Workers

8. PAHO's Recommendations for Setting up and Operating a Successful Salt Fluoridation Program

A salt fluoridation program's long-term survival depends on the active participation of local authorities and the country's salt industry. PAHO's Regional Oral Health Program recommends that a country technical officer (CTO) be designated in each country to act as a liaison between health authorities and the salt industry, and as project coordinator and educator for the program. This person also would provide assistance on disbursing funds and would coordinate consultant work dealing with project components under development. The CTO's additional functions would involve attending periodic meetings of the country's salt fluoridation commission, expediting the development of legal documents designed to enforce salt fluoridation, and providing coordination and assistance in identifying funding sources for aspects of the program that might not be funded by external or internal donors.

PAHO's Regional Oral Health Program, through the Organization's Advisory Board on Oral Health Programs, issues recommendations for improving projects and sets protocol guidelines and specific requirements based on scientific evidence. Research and country studies are discussed, and a consensus is presented to the project directors in the countries for implementation. In February 1998, the Regional Oral Health Program convened a group of scientific experts in Washington, D.C., to evaluate technical aspects of salt fluoridation programs, using existing scientific evidence as a reference. That group submitted recommendations to PAHO, which were approved by representatives of salt fluoridation programs in 19 countries at the First Regional Workshop on Salt Fluoridation held in Quito, Ecuador, in July of the same year.[1] The recommendations included issues such as which type of salt fluoridation program should be maintained in each participating country, which programs needed to be phased out, and what instruments to use for data collection to monitor program implementation. The last item is an extension of monitoring sections included in the overall proposal. The recommendations also stressed two qualifiers. *Essential items* are those that must be implemented because they are vital for the success of the program. *Non-essential recommendations* are important but not vital; non-essential recommendations could be optional.

[1]Organización Panamericana de la Salud. Taller Regional de Vigilancia epidemiológica y Control de Calidad de los Programas de Fluoruración de la Sal. Primer Simposio Internacional sobre el uso de fluoruros como medida preventiva de caries dental. Quito, Ecuador, 27 al 30 de julio, 1998. Informe final.

The recommendations issued during the Quito workshop, which remain valid, are the following:

RECOMMENDATIONS

1. Only one systemic source of fluoride is recommended for each country. This should be either salt or water, but not both.
2. Dental caries should be monitored to evaluate the effectiveness of the preventive program. Both baseline and follow-up studies are recommended (however, only the baseline study was within the scope of the grant proposal). The baseline survey of dental caries is essential and should target children 6, 8, 12, and 15 years old The recommended survey uses a tooth-based index (DMFT) and the diagnostic criteria and coding recommended by WHO. In addition to the DMFT, which is essential, a surface-based index (DMFS) provides specific information about different types of caries predilection sites with strongly differing davier-proneness (fissures and pits, approximal surfaces, free smooth surfaces) but is not mandatory for assessment of the public health impact of the preventive program.
3. Dental fluorosis indicates past exposure to fluoride and should be monitored to assess unacceptable cosmetic effects of systemic fluoride overuse during years when permanent teeth are developing. Dental fluorosis is to be measured by a modified version of Dean's Index that includes only the upper anterior teeth (cuspid to cuspid). Only the facial surfaces should be evaluated using the six categories described by Dean. Other teeth, while not essential, could be included.
4. Urinary fluoride excretion should be monitored to evaluate current exposure to fluoride. The target population for urinary fluoride excretion studies involves children 3–5 years old. This study, although highly recommended, was considered non-essential. According to WHO recommendations, these studies should be carried out immediately before introducing systemic fluoride and then 6 and 12 months after initiation. PAHO's recommendations were modified to include only one evaluation, 24 months after the program was initiated, but stated that a baseline study could be included if the country considered it necessary. A 14–18 hour period was considered an acceptable protocol for urine collection (*1*). In addition, this study should be conducted in clusters of 30–35 children in communities with suboptimal, optimal, and above-optimal concentration of fluoride in drinking water; follow-up studies should include communities were fluoridated salt is distributed.
5. Conducting a baseline study of fluoride concentration in water for human consumption is essential. In all participating countries, fluoride occurs naturally, and its concentration may vary seasonally and as a result of geological activities. Consequently, all water sources with fluoride concentrations above 0.5 ppm should be monitored on an ongoing basis to avoid overexposure were the fluoride content of the water to increase after the introduction of salt fluoridation.
6. A nutritional survey to determine the consumption and ingestion of salt is considered non-essential. Data from previous nutritional studies could be used.
7. Regarding additional sources of fluoride intake:
   a. The use of dietary fluoride supplements such as drops, tablets, or multi-vitamins that contain fluoride should be stopped. This recommendation could be carried out by monitoring the presence of these products in the market and by conducting surveys of health practitioners or parents.
   b. In a country that has a national systemic salt fluoridation program in place, programs advocating the use of fluoride mouth rinses to provide additional topical preventive effect should not be put in place if the DMFT at age 12 falls below 3. In countries that do not have a national salt fluoridation program, fluoride mouthrinse programs should be continued if the DMFT index is greater than 3; if the index is less than 3, these programs can continue

if they have been shown to be cost-effective. Fluoride mouth rinses should only be provided to children older than 6 years; at this age, the swallowing reflex is sufficiently developed to avoid accidental ingestion of the product. Even if these older children swallow the product, the effect on dental fluorosis is negligible because most anterior teeth have been fully formed at this age.

c. The use of fluoridated toothpaste is highly recommended. In children younger than 6 years, only a pea-sized portion of toothpaste should be delivered by the parent/guardian. Moreover, toothbrushing with fluoride toothpaste by children under 3 years old should be supervised directly by the parent or guardian. It is recommended that children under 6 years old should use toothpaste with a fluoride concentration between 400 and 550 ppm. Children older than 6 years should use the standard formulated fluoride toothpaste (between 1,000 and 1,500 ppm). A baseline survey followed by periodic surveys of toothpaste use are part of the ongoing monitoring recommendation. Periodic evaluations could be performed thorough sales and import data.
d. Oral health promotion and toothbrushing training should continue after the implementation of national programs using systemic fluoride.

8. The recommended range of fluoride concentration in salt for human consumption is 200–250 mg/k (equivalent to 250 ppm F). The actual concentration should be adjusted based on the level of urinary fluoride excretion, the level of fluoride in the drinking water, and the prevalence and severity of fluorosis that accounts for the time-lapse between when fluorosis is observed and when exposure occurred.
9. Countries should assess the existing and regulatory framework that supports or hampers the introduction and sustainability of fluoridation programs. This requires the review of existing laws and regulations, and the promotion of new or supplementary ones. Also, a regulatory mechanism for quality control should be part of the regulations concerning dosage. The Regional Oral Health Program will promote the introduction of fluoridated salt in the Codex Alimentarius.
10. Continuing education to the public and to health professionals is essential.

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9. A Legal Framework for Mandatory Iodization and Fluoridation of Salt

In this era of expanding international trade, laws establishing product standards have become increasingly important. Furthermore, strict quality control of a food product such as salt is necessary to protect consumers and to ensure the effectiveness of salt fluoridation programs. The Pan American Health Organization studied existing legislation covering salt iodization as a way to issue recommendations for the enactment of unified legislation and standards for salt iodization and salt fluoridation. Working with a lawyer consultant and using existing legislation from Mexico and Ecuador as a basis, PAHO came up with the legislative blueprint that is presented in this section. Countries wishing to enact such legislation can use it as is, or may modify it to suit their particular circumstances.

WHEREAS:

I. Iodine and fluoride deficiencies are a serious health problem for the country due to their impact on both health and the economy;

II. Their rising incidence causes significant deterioration, mainly in the population with limited economic resources;

III. One of the most effective preventive measures against iodine deficiency disorder and dental caries consists of the addition of iodine and fluoride to salt destined for human consumption;

IV. The success achieved in the eradication of endemic goiter in the Americas through mass consumption of iodized salt indicates that salt would also be an appropriate vehicle for fluoride intake.

THE FOLLOWING IS DECREED:

Unified Regulations Of The Law On Mandatory Iodization Of Salt For Human Consumption And The National Fluoridation Program

Section I.

Definitions

Art. 1. "Salt for human consumption without other additives" is the designated term for the commercially pure or purified product chemically identified as sodium chloride, extracted from natural sources. It is found in the form of colorless crystals that are soluble in water and have a clear salty taste; its consumption is authorized by the Health Authority. Excluded from this definition is salt utilized for non-dietary industrial purposes.

Art. 2. "Salt destined for human consumption" is considered to be for both direct and indirect consumption.

Art. 3. "Salt for direct human consumption" is understood as that used in the kitchen and at the table in the preparation and seasoning of food.

Art. 4. "Salt for indirect human consumption" is understood as that utilized in the food industry as a preservative and seasoning and, in general, as an additive in food processing.

Art. 5. "Salt for animal consumption" is the term used for the product made from sodium chloride that is utilized only in the feeding of animals.

Section II

General Sanitary Regulations

Art. 6. The periodic monitoring of salt for human consumption is the exclusive function of the Ministry of Public Health through the corresponding department.

Art. 7. All salt produced in the country for direct human consumption (domestic salt)—that is, table salt and kitchen salt—must be iodized or iodized and fluoridated prior to its sale.

Art. 8. Salt for human consumption, listed by the characteristics, purity, and granulation indicated in these Regulations, is classified into three groups: ground salt, refined salt, and table salt.

Art. 9. Salt for human consumption should be presented in the form of white cubic crystals, bonded together to form small pyramids with a quadrilateral base.

The different types of granulated salt must be uniform within each type. In addition, they must be free of nitrites, impurities, and microorganisms that would indicate improper handling of the product—that is, coliform and other pathogenic and chromogenic microorganisms must not be present. The basal germ count may not be higher than 20,000.

Art. 10. Ground refined salt is the product treated to eliminate hygroscopic magnesium and calcium salts, organic impurities, sand, and shell fragments; the crystals should pass through a No. 20 mesh sieve and at least 25% should pass through a No. 60-mesh sieve. Furthermore, its physical and chemical characteristics should satisfy the criteria and standards with the following limits:

- Moisture no greater than 2% at 150°C.
- Insoluble residue in water no greater than 0.3%.
- Sodium chloride (on a dry basis, free of antihumectants) no less than 98%.
- Degree of turbidity no greater than 25%.

Art. 11. Table salt has the same granulation and physical and chemical constants as those established for refined salt, except that the moisture content should not exceed 0.5%. This limit requires that antihumectants be added, not to exceed 2%; this will allow sodium chloride content to fall to 96%.

Art. 12. Salt for direct human consumption should be iodized, or iodized and fluoridated, and should meet the specifications and sanitary standards for each type as described here. It should contain iodized salt, a product consisting basically of sodium chloride ($NaCl$), to which has been added potassium iodate or sodium iodate ($KIO3$ or $NaIO3$, respectively) or potassium iodide (KI), and which has a free iodine concentration no greater than 75 mg/kg of salt, with a tolerance of ±25 mg/kg of salt. These concentrations may be modified by the Ministry of Public Health, in response to the findings of the respective nutritional surveys and when justified by epidemiological studies on iodine dosage.

Art. 13. Iodine should be added only by using potassium iodate or sodium or potassium iodide. Fluoride should be added by using sodium fluoride or potassium fluoride (NaF or KF, respectively), in accordance with the dry or wet method of production.

Art. 14. Salt for human consumption destined for manufacturing industries other than the food industry is exempt from fluoridation.

Art. 15. Salt for human consumption must be packaged in new containers that preserve the product's integrity, offering adequate protection against contamination and moisture. Packaging material that comes in contact with the product must not be broken down by the product and must have properties so that it does not alter the product's taste or smell.

Art. 16. Establishments and facilities involved in the industrial production of salt for human consumption also must comply with the general requirements stipulated by the Sanitary Code and the present Regulations.

Art. 17. The production and fractionation of iodized salt for indirect use may only take place in facilities previously authorized by the health authority and the Ministry of Public Health.

Art. 18. Individual or corporate entities that own the facilities mentioned in Art. 17 must comply with the requirements established by the Sanitary Code.

Art. 19. Centers for the production, fractionation, packaging, or repackaging of iodized salt and fluoridated iodized salt or of salt for indirect human consumption must also comply with technical requirements stipulated in the section of the Sanitary Code that applies to environmental sanitation and equipment.

Art. 20. In order to guarantee the correct addition and persistence of iodine and fluoride in the salt, the producer must use an efficient, economically feasible process, utilizing the wet method which guarantees homogeneous distribution of the elements, so that a random sample satisfies the requirements for content of iodine and of fluoride established in the present Regulations.

Art. 21. Imported salt for direct or indirect human consumption that is marketed in the country must comply with the specifications in the Law with regard to physical, chemical, and microbiological properties and the addition of micronutrients (iodide or iodide and fluoride).

Art. 22. Plants that refine and purify salt for human consumption must have stainless steel equipment, given the high degree of corrosion that this raw material causes.

The plant will consist of:

(a) A drum dryer that produces a contiguous salt curtain, purifying it and raising its temperature to 120°C throughout.
(b) A cyclone turbine system that removes impurities that become separated from the product as it passes through the drum dryer by means of a strong current of air.
(c) Screening equipment with stainless steel mesh to avoid contamination of the product by rust.
(d) Mechanized transport from one stage of the process to another, with no operator coming into contact with the product.
(e) Precision mixer, given the low dosage of potassium iodide and sodium or potassium fluoride to be incorporated. This is a vertical conic mixer with highly precise epicycloidal movement that consists basically of a conic shaft with an Archimedes' screw incorporated in its interior to provide the homogenization of the mixture required by the Ministry of Public Health.
(f) Fully automated packaging for salt for human consumption in which the full cycle can run its course without human hands touching the product once it has been refined.

The equipment detailed above is the minimum required for these processes. Quality control must be exercised in incorporating iodine and fluoride: two samples must be collected from each batch from the mixer, labeled with the date and batch number, and analyzed; the information must be made available to the Ministry of Public Health for 45 days. Salt refining and purifying plants, as well as facilities for packaging salt for human consumption, must be licensed by the Ministry of Public Health.

Section III

Container and Labeling

Art. 23. Packaging of iodized and iodized fluoridated salt for direct consumption must be carried in strict compliance with the conditions stipulated in Art. 15 of these Regulations.

Art. 24. The container for the sale of iodized and iodized fluoridated salt must bear a visible label in the country's official language with clear lettering that shows the name and patent, if any, as well as the following:

- The designation "iodized salt for human consumption" or "iodized fluoridated salt for human consumption."
- The net contents of the product in the container, expressed in decimals.
- Name and location of the manufacturer, sanitary registration number, and patent and lot numbers.
- The wording, "Manufactured in its country of origin."
- Declaration of the additives used.
- Warning, in the case of fluoridated iodized salt: "Do not consume or sell this product in areas where water for human consumption has fluoride levels higher than 0.7 ppm.

Art. 25. The container for the sale of salt for indirect human consumption must bear a visible label in the country's official language, stating:

1. The designation: "Salt for use in the food industry."
2. Net contents expressed in decimal metric system units.
3. Name and location of the manufacturer, sanitary registration number, patent and lot numbers.

Section IV

Monitoring and Sanctions

Art. 26. The technical sections of the Ministry of Public Health shall keep a record of the plants that produce salt for human consumption. These records provide such technical information as production volume, types of products manufactured, salt distributors, and other necessary data for efficient control.

Art. 27. Individuals, corporations, commercial firms, etc., listed as owners of factories or establishments that produce, package, or repackage iodized salt for the food industry, and fortified salt with iodide and fluoride for human consumption, shall be directly responsible for all products delivered for sale that have production defects or packaging deficiencies. No excuse aimed at reducing or avoiding such responsibility shall be accepted.

Art. 28. The centers where iodized salt and fortified salt with iodide and fluoride are sold, such as supermarkets, warehouses, and grocery stores, that dispense salt that does not comply with the provisions of the present Regulations shall be sanctioned in accordance with the penalties established in the Sanitary Health Code.

Art. 29. Every salt iodization and fluoridation plant must maintain quality control records of the production process. These records must be available to the health or trade authorities that request them.

Art. 30. Salt destined for nonfood industrial use and that is considered unsuitable for human consumption is exempt from the above requirements.

Art. 31. The establishments that produce salt for direct or indirect human consumption must comply with the sanitary and hygienic standards established in the Sanitary Health Code and these Regulations.

Art. 32. Permission to possess common non-iodized and non-fluoridated salt is granted only to the concession-holders of deposits being exploited, to manufacturers that refine it or that iodize and fluoridate it, and to those that utilize it for nonfood industrial purposes.

Art. 33. The marketing of nationally produced or imported salt for direct or indirect human consumption that does not comply with the requirements in the previous articles, shall be regarded as a crime against the public health, and those responsible will be sanctioned as provided by the Penal Code.

Art. 34. The National Health Authorities (Ministry of Public Health) of each country will enforce all provisions in effect on hygiene, quality, iodine and fluoride content, and packaging of salts for direct and indirect human consumption, salt for use in the food industry, and salt for animal consumption established in the present Regulations.

Art. 35. Producers of iodized and fluoridated salt for direct and indirect human consumption, salt for the food industry, and salt for animal consumption and refiners, packagers or repackagers that sell or distribute salt that do not comply with the provisions in the present Regulations will be sanctioned in conformance with the penalties established in the Sanitary Health Code.

Art. 36. When violation of the requirements of quality, iodization, or fluoridation has been verified, the producer or dealer will be sanctioned as established in the Sanitary Health Code.

Art. 37. Verification of the chemical specifications of fluoride established in these Regulations will be carried out using a potentiometer with fluoride ion-specific and reference electrodes.

Art. 38. Manufacturers of containers for iodized and fluoridated salt may make them only for persons or companies whose sanitary registration is up-to-date, and every month must submit the list of containers made for salt to the salt fluoridation program.

Temporary Provisions

Country-specific Recommendations

- Tariff barriers should not be considered the basic criteria for these Regulations.
- Social policies and sanitary criteria should prevail over business and/or commercial considerations from trade agreements (such as

the North American Free Trade Agreement (NAFTA), Mercado Común del Sur (MERCOSUR), and the European Economic Community (EEC).

- Laws, decrees, and regulations should be reviewed so that the programs are implemented effectively.
- The introduction of iodized salt and iodized fluoridated salt (where addition of fluoride is necessary) within the food code should be compulsory.
- Regulations on the additional use of fluoride should be reviewed to reduce the risk of fluorosis.
- Strict monitoring of the salt industries, taking into account both quantitative and qualitative considerations, should be put in place.
- Strict monitoring of the public sector—particularly epidemiological surveillance and quality assurance of fluoridated salt—should be instituted.
- International agreements with respect to foreign trade (import and export) should be fixed.
- The government's support for the programs should be ensured.

10. Standardized Research Protocols

The three protocols included in this section are meant to be used by oral health care providers and researchers for collecting and reporting information on salt fluoridation programs. They provide a systematic approach for the collection of data, enabling these health workers to make standard measurements of oral diseases and conditions as a basis for planning and evaluating salt fluoridation programs. They also ensure that the data collected is comparable across countries.

The protocols were developed by PAHO's Regional Oral Health Program with the support of a core group of consultants—notably Eugenio Beltrán, Herschel S. Horowitz, Ramón Baez, and Oswaldo Ruíz—and the participation of all the countries that have salt fluoridation programs. This team took WHO standard protocols for determining caries, fluorosis, and fluoride excretion in children as the foundation, and modified them for this purpose.[1]

1. EXAMINATION PROCEDURES AND CODING FOR VISUAL-TACTILE ORAL HEALTH SURVEYS[2]

Introduction

A dentist examining an individual patient and an epidemiologist determining the prevalence of dental disease in a population share many of the same working methods. But there are important differences in their goals.

The dental clinician follows diagnostic criteria and procedures intended to determine the patient's oral health needs. With that in mind, the dentist compiles an inventory of signs and symptoms, and uses X rays and other diagnostic tools to supplement the information obtained by direct observation.

In contrast, the epidemiologist looks for descriptors of oral health conditions in a population. The epidemiologist's goal is to quantify the prevalence of disease conditions in the population and to track changes in those conditions over time. Oral epidemiology studies—such as open-mouth surveys—require the examination of a large number of subjects and, usually, the participation of several examiners. Further, the epidemiologists' diagnostic criteria and methods emphasize the reproducibility of results, rather than meticulous detection of the earliest sign of disease. To maximize reproducibility, epidemiologic methods use conservative diagnostic criteria, relying on unambiguous visual evidence of pathology, rather than the more sensitive clinical or radiographic diagnostic aids used in a dental practice. The process by which examiners and their recorders (persons recording the data) learn these criteria and methods is called standardization; quantifying the level of standardization is called calibration.

Why are standardization and calibration of examiners and recorders so important in epidemiologic studies? In data collection, two of the most important issues are validity and reliability. Bias is the main threat to data validity. We all have biases, which, even after professional training, can affect

[1]The three protocols in this chapter originally appeared in PAHO's Regional Oral Health Program's "Final Report to the W.K. Kellogg Foundation," Project #43225, Multi-Year Plan for Salt Fluoridation programs in the Region of the Americas (Belize, Bolivia, Dominican Republic, Honduras, Nicaragua, Panama, Venezuela), published in Washington D.C. in 2000.
[2]Adapted from WHO's Oral Health Surveys, Basic Methods 4th edition, 1997.

our ability to be objective. To diminish bias, we must establish strict diagnostic criteria for each disease or condition we intend to examine. This is what is meant by standardization.

However, establishing strict standard criteria is not the only requirement for high-quality data. Physical and psychological factors such as fatigue, uneven interest, indecisiveness, and variations in visual acuity and tactile sense can affect the judgement of examiners. To reduce these factors, a system that checks the reliability of examiners and recorders must be implemented during the examination process. This reliability checking is what is meant by calibration. Reliability must be assessed between examiners (interexaminer reliability) and in each examiner (intraexaminer reliability).

The process of standardization and calibration has two phases. First, oral health care providers must study and memorize the diagnostic criteria and procedures described in this chapter. Second, they must undergo a calibration exercise in which they will be asked to apply the criteria and methods in a setting similar to that which will be found during field-data collection.

Summarizing, the objectives of calibration for epidemiologic studies are (*1*):

1. To ensure uniform interpretation, understanding, and application of diagnostic criteria for the various diseases and conditions to be observed and recorded.
2. To ensure that each examiner can examine to a uniform standard.
3. To minimize variations in examiners and between examiners.

This protocol is divided into two main sections. The first explains the procedures that must take place immediately before the oral examinations. The second section provides the coding for different oral health conditions to be included in the epidemiologic survey. Each coding scheme is followed by notes and special considerations. These notes are important, and in reading the chapter you will come to understand when and why these points are applicable before the calibration exercise.

The latest version of the data entry form ("Sample Data-Entry Form Used to Survey Schoolchildren") appears on page 105.

General Instruction and Procedure for Examination

As an examiner, you will receive from the survey planner a list of schools to visit and a guide to the procedure that should be used to select children from the school. It is important that you follow these instructions, as the validity of the survey depends on your ability to randomly select children from every school that is part of the survey.

The survey planner also will make available to you equipment, instruments, and materials for conducting the survey. The equipment should be arranged in a room within the school. This room should have access to power outlets, appropriate ventilation and cooling, a waiting area with enough chairs to accommodate participating children, access to a nearby water faucet for washing hands and instruments, and access to a garbage bin for discarding used material. You will receive an infection-control protocol that must be followed during the entire examination process.

When you arrive at the school the day of the examination you should first contact the principal, whom the survey planner has notified of the day and time of your visit. The principal can help you appoint a person from the school staff to coordinate the movement of children from classrooms to the examination room so as to cause the least possible disruption. If your survey includes a parental consent form, each child should bring the form to the examination area.

You will need three chairs to carry out the examination: one for yourself, one for the recorder who will be writing your diagnosis codes during the examination, and the third for the child being examined. The codes will be written down on a paper form (see "Sample Data Entry Form on page 105) or entered into a data-entry program on a laptop computer. Before the child sits in the chair or lies on the examination table, the recorder collects the consent form and transfers the information (identification number, sex, birth date, age) to the paper form or data-entry program. After putting on your gloves and before starting the examination, you will ask for the final parental agreement releasing the child for the examination. You are now ready to collect data on the following conditions:

- Dental fluorosis in children aged 12, 15, and adults 35–44.
- Coronal caries/sealants and treatment needs in children aged 5, 12, 15, and adults 35–44.
- Prosthetic status in adults 35–44.
- Prosthetic needs in adults 35–44.
- Urgency of treatment for all ages.

Once you have collected this information, the recorder will transfer the value you have assigned for "urgency of treatment" to a form with the name of the person examined. This form should be returned to the teacher for distribution or handed to the child or adult.

Each examination will take less than five minutes and will require your systematic visual or tactile observation and diagnosis of the teeth or surfaces selected. Once you have reached a diagnosis for each tooth or surface, you will provide that information to the recorder. You should not need to identify the tooth for which you are providing the code, because the examination is carried out sequentially and all boxes in the form or data-entry program are filled out accordingly. However, for consistency's sake, each tooth should be identified using the World Dental Federation (FDI) codes shown below.

For assessing dental fluorosis, you should always start on tooth 13 (upper right cuspid), follow toward the midline, and continue to tooth 23 (upper left cuspid). A total of six codes will be provided to the recorder.

For assessing dental caries/sealants and treatment needs, you will start with tooth 17 (upper right second permanent molar) and continue toward the midline, ending in the maxillary jaw with tooth 27 (upper left 2d permanent molar). You will then continue with tooth 37 (lower left second permanent molar) and then follow in the opposite direction toward tooth 47.

First, you will provide the code for each surface-caries status, meaning five numbers for molars and premolars and four numbers for incisors and cuspids (no occlusal surface). In providing the surface code for each tooth you will always follow the order of mesial, distal, buccal, lingual.

Once you have finished with the surface data you will provide one additional code corresponding to the treatment need for that entire tooth.

For determining prosthetic status and needs you will assess the entire mouth following the same pattern as in the assessment of caries. You will provide two codes, one for status and one for needs. These codes apply to the entire person.

Finally, based on your observations, you will explain the code—to the child's parents or to the adult that has been examined—regarding the urgency of need for treatment.

Important Notes:

1. In this survey you will use the FDI codes that correspond to permanent teeth. The same spaces (cells in the sample data-entry form) will be used for the primary dentition. Differentiation between a primary and a permanent tooth will be done based on the code used (mostly numbers for permanent teeth, and mostly letters for primary teeth).
2. Third molars are excluded from examination.
3. It is important that the examination and recording follow the same path within the mouth in all subjects. Do not skip teeth or surfaces.
4. The recorder should understand that the examiner will provide six codes for the molars

Upper right quadrant | Upper left quadrant

17	16	15	14	13	12	11	21	22	23	24	25	26	27
		55	54	53	52	51	61	62	63	64	65		
47	46	45	44	43	42	41	31	32	33	34	35	36	37
		85	84	83	82	81	71	72	73	74	75		

Lower right quadrant | Lower left quadrant

CODING FOR DENTAL FLUOROSIS:
Tooth-based coding for upper anterior teeth—cuspid to cuspid.

Code	Diagnostic criteria
0	**No Fluorosis:** The enamel surface is smooth, glossy, and usually a pale creamy-white color.
5	**Questionable:** The enamel shows slight aberrations from the translucency of normal enamel; aberrations may range from a few white flecks to occasional spots, usually, but not always, located on the incisal third of the surface.
1	**Very Mild:** Opaque, paper-white areas or lines the thickness of a pencil mark scattered irregularly over the tooth but involving less than 25% of the surface. Many times the hypocalcifications follow the perikimata lines.
2	**Mild:** The white opacities on the enamel extend to more than 25% but less than 50% of the surface.
3	**Moderate:** The amount of enamel affected extends to more than 50% of the surface. Sometimes the hypocalcified enamel captures particles and chromogenic bacteria from the environment and saliva, changing the enamel from white to brown.
4	**Severe:** This code is applicable to any of the previous classifications combined with the presence of distinctive unique or confluent pits. Pits correspond to enamel that is lost after eruption. Single pits are diagnosed with an explorer and should have delimited walls in most of the pit's circumference. The bottom of the pit can have normal enamel or fluorotic enamel with or without brown coloration. Brown coloration is not a sufficient criterion to code "severe."
8	**Not recorded:** This code is applicable to any partially erupted tooth or any tooth cover with a crown or orthodontic band/bracket.
9	**Excluded:** Applicable to any primary tooth.

and five for anterior teeth (including treatment). Since this is done sequentially, it is a good idea if the examiner says a key word (e.g., "check" or "midline") after he or she has reached the final code for tooth 11, 27, and 31. This allows the recorder to check his or her synchronization. If there is no congruency in the sequence, the examiner should restart in the first tooth of the quadrant.

5. The examiner will call out a total of 169 codes for each person, regardless of the person's age. These correspond to the 169 available cells in the clinical section of the data entry form.
6. All spaces in the data entry form should be filled in before the person leaves the examination area. There are special codes for each variable when the person, because of age, does not qualify for a specific examination.

Special Diagnostic and Clinical Situations during Examination for Dental Fluorosis

Only fully-erupted teeth are scored, using a good source of artificial light. The teeth should *not* be dried before scoring.

A tooth is not evaluated for fluorosis if one-third or more of the visible enamel area is replaced with a restoration or is destroyed by caries or covered with an orthodontic band.

Staining per se in otherwise intact enamel is not a diagnostic criterion specific to any of the classifications.

Fluorosed teeth do not erupt with pits. Instead, pitting occurs post-eruptively when teeth are subject to masticatory forces. A pit is defined as a discrete, focal loss of outermost enamel. The defect is partly or wholly surrounded by a wall of enamel. Initially, the enamel wall is usually intact. But with wear, the enamel wall can be abraded, so that often only part of the enamel can be detected. In contrast to intact enamel on which the explorer tip can be moved easily across the smooth surface, pitted areas demonstrate a definite physical defect in which the base of the defective area may be either carious or sound. If it is sound, the base of the pit is rough and offers resistance to the lateral movement of the explorer tip; a scratchy sound is detected when the explorer is moved across it. If the base is carious, it demonstrates softness upon being probed with moderate pressure. In either case, the pitted area is usually stained or a different color compared to the surrounding enamel.

CODING FOR DENTAL CARIES: Surface-based coding.

Code for Primary Teeth	Code for Permanent Teeth	Diagnostic Criteria
A	I	**Sound:** A sound surface is one without any signs of cavitation due to decay, sequelae (restorations), or a sealant. If the surface has lost part of its structure due to fracture or trauma it is considered sound. Pits and fissures represent a special situation. Any surface with less than 25% of its pits and fissures showing coloration will be considered sound; otherwise, it will be considered as a non-cavitated lesion (see codes L and U).
N	U	**Noncavitated lesion:** This code applies only to surfaces with pits and fissures showing more than 25% coloration (brown to black) without clinical signs of decay, i.e., decalcification or undermining of surrounding enamel or demineralized dentin at the bottom of the fossae/fissure.
B	1	**Decayed:** Three types of lesions can be coded as decayed: 1) Pit-and-fissure caries lesions—defined as the presence of a cavitation or decalcification or undermining of the surrounding enamel (with a change of color to dark) or soft dentin at the bottom of the pit or fissure. The explorer should be used *only* to confirm the presence of soft dentin and *only* when diagnosis cannot be made with the naked eye. 2) Free-surface caries lesions—lesion on any other surface that does not have pits or fissures. (These surfaces include the entire mesial and distal surfaces and the buccal surfaces of anterior teeth; lingual surfaces of upper anterior teeth and sometimes the lower anterior teeth can have pits.) In the buccal surfaces (nonproximal), the diagnosis is reached when there is clear evidence of cavitation. In the anterior proximal surfaces, the diagnosis can be reached using the mirror to transilluminate the proximal area. In the posterior proximal surfaces, the examiner needs to detect the presence of the cavity with the explorer (changes in color in the marginal reach are not enough to diagnose proximal decay). 3) Secondary caries next to a restoration—Diagnosis is reached if you can detect with the explorer the presence of soft dentin. A gap between the restoration and the tooth is not enough of a criterion to diagnose caries. Any temporary restoration is considered as decayed.
C	2	**Filled:** A filled surface includes any surface that has been restored partially or completely with a restorative material *as a direct consequence of decay*. Restorative materials include silver amalgam, crowns (stainless steel or cast), inlays, composite resins, silicates, and glass ionomers.
D	3	**Missing due to caries:** This code applies to any surface from any tooth that has been extracted as a direct consequence of caries. In the primary teeth, the code D will be applied to *all* empty spaces in the primary molar area up to age 8 (8 and 11 months). If the child is 9 or older, these spaces are coded as unerupted permanent (code 9). Any empty space in the primary anterior area at any age also will be coded as unerupted permanent (code 9). In older cohorts, it will be difficult to assess if the tooth has been extracted due to caries or periodontal diseases, or because a dentist decided to extract the tooth for prosthetic reasons. In all these cases the code assigned should be 3.
E	4	**Missing for other reasons:** This code applies to any surface of any tooth that has been lost for reasons unrelated to caries, i.e., due to trauma or orthodontic treatment.
F	6	**Sealant present:** Total or partial sealant present *only* in occlusal surfaces of permanent or primary teeth. This includes sealants on parts of the occlusal surface that have been slightly enlarged from using a round bur to eliminate suspicious carious tissue. Sealants on fissures from buccal or lingual surfaces of molars or incisors are *not* included. A restoration with a composite resin which required a full preparation is *not* considered a sealant.
H	7	**Bridge abutment:** This code applies *only* to any tooth prepared as an abutment in both anterior or posterior teeth.
	8	**Implant:** This code applies *only* to the presence of crowns associated with an implant.
	9	**Unerupted tooth:** Applies only to spaces in the arch with primary teeth absent due to normal shedding *and* before any clinical signs of the erupted permanent tooth can be distinguished.
K	T	**Trauma:** Applies to untreated fractures, changes in color in the entire crown, restoration involving the incisal edge, and anterior crowns installed due to trauma.
L	X	**Excluded:** This code applies to all surfaces in specific situations, including anterior crowns added for cosmetic reasons. It also applies to teeth that cannot be assessed completely because they are partially covered with orthodontic bands or brackets.

Special Clinical Situations

- Incisal edges of anterior teeth are not considered separate surfaces. If a lesion or restoration is confined solely to the incisal edge, its score should be assigned to the nearest adjacent surface.
- When a filling or lesion on a posterior tooth, or a caries lesion on an anterior tooth, extends beyond the line angle onto another surface, then the other surface is also scored as affected. However, a proximal filling on an anterior tooth is not considered to involve the adjacent labial or lingual surface unless it extends at least one-third into that surface. The reason for this is that tooth structure on adjacent surfaces often must be removed to provide access for the restoration of a proximal lesion on anterior teeth.
- In this survey there is no independent code for crowns in either dentition. Therefore, if a posterior tooth has a full-crown restoration placed because of caries, you should code for the three surfaces filled due to caries (code 2). These surfaces are the mesial, occlusal, and distal. If an anterior tooth has a full-crown restoration placed because of caries, you should provide codes for the two surfaces filled—the mesial and distal. By convention, all crowns on posterior teeth, excluding abutment teeth for fixed or removable prostheses, are considered to have been placed as a result of caries. On anterior teeth, however, the examiner makes the determination of the reason for crown placement. If the crown was placed for any reason other than caries—such as fracture, malformation, or aesthetics—the tooth is coded as excluded (code X).
- If a tooth has been restored with less than full coverage, all surfaces not involved should be scored in the usual manner.
- Some teeth, typically the first bicuspids, are extracted for orthodontic reasons. Label these as missing for other reasons (code 4). To recognize these patients, check the status of the contralateral bicuspid and look for evidence of orthodontic treatment. Be aware that other teeth may be extracted for orthodontic reasons. In most cases, former or current orthodontic patients will recall having had extractions.
- Nonvital teeth are scored in the same manner as vital teeth. Therefore, restorations on the lingual surfaces of anterior teeth used as entry for root-canal therapy *should not* be recorded as restored. Code this surface as sound.
- Hypoplastic teeth are scored in the usual manner. However, if a restoration on such a tooth was placed solely for aesthetic reasons, that restoration will not be scored. If a hypoplastic tooth is restored with a full crown, it is coded as excluded (code X).
- Malformed teeth are scored in the usual manner, except when they have been restored with a full crown for aesthetic reasons, in which case they are coded as excluded (code X).
- When the tooth crown is destroyed by caries and only the root remains, score all surfaces as carious.
- Fractured or missing restorations are scored as if the restorations were intact unless there is caries. If caries is found within or adjacent to the margins of a fractured or missing restoration, caries should be scored only in the surfaces involved.
- In the case of supernumerary teeth, only one tooth is called for the tooth space. The examiner must decide which tooth is the main occupant of the space.
- If both a primary and permanent tooth occupy the same tooth space, score only the permanent tooth. There is a hierarchy in coding when more than one code is possible. Sound surfaces/teeth are at the bottom of the hierarchy. Sealed surfaces/teeth have precedence over sound surfaces/teeth. Restored surfaces or teeth have precedence over sealed surfaces/teeth. Finally, surfaces/teeth with untreated have precedence over restorations.
- In general, when the same tooth surface is both carious and filled (e.g., upper permanent molar with mesial pit filled and distal pit with caries), code for caries.
- Third molars are not scored. When examining second molars it is important to note that a drifted molar may occupy the space of a missing second molar. In such cases, the diagnosis and call must apply to the status of the missing second molar, not the third molar. If the second

molar, for example, was extracted due to caries and the space is now occupied by a sound third molar, the second molar is scored as missing due to caries (code 3).

- A tooth is considered erupted if any of its clinical crown projects through the gum.
- Stain and pigmentation alone should not be regarded as evidence of decay, since either can occur on sound teeth.
- A surface is coded as sealant present if *any* part of the surface remains covered with the sealant. In most clinical situations, the sealant covers the surface's pit and fissure. Remember that sealant products vary widely in color and you may need tactile confirmation of the presence of sealant.
- If you are sure that a composite material has been used as a restoration (i.e., it required preparation using a rotary instrument) in all or part of the fissure, then score the surface as filled. In case of doubt and if there is composite material present, code the surface and tooth as sealant present.

Important Information when Coding Caries Prevalence Using a Paper Form

In this type of survey, you will be collecting surface data for caries. However, certain codes are applicable to all surfaces. The examiner can save time by following the code with the the word "all." The recorder will know that the preceding code applies to all surfaces and will write the code for the mesial surface and a horizontal line across the remaining surfaces. Then, the following number will correspond to the code for treatment needed for that tooth. The codes for which this shortcut applies are:

Sound (A, 1), missing, both due to caries and for other reason (D,E,3 and 4), bridge abutment (7), implant (8), unerupted tooth (9), and excluded (X).

NEED-FOR-TREATMENT CODING: Tooth-based Coding.

Code	Diagnostic Criteria
0	**No need for treatment:** The crown is sound or has a restoration in good condition (no secondary caries).
F	**Fissure sealant:** A permanent molar will be eligible for sealant if the following three conditions are present: (1) tooth is within three years of eruption; (2) there is an obvious "catch" during examination with the probe; and (3) there is at least one additional restoration in any other pit and fissure. A primary molar will be eligible for sealants if conditions (2) and (3) are present.
1	The tooth needs one surface restoration.
2	The tooth needs two or three surface restorations or multiple restorations in combinations of one, two, or three surfaces.
3	The tooth needs a crown for any reason.
4	Veneer or laminate for aesthetic reasons (anterior teeth).
5	**Pulpar care and post-treatment:** The tooth probably needs pulpar care and, later, a restoration with a filling or crown. Pulpar care could be needed as a consequence of caries or trauma. Pulpar care includes treatments (e.g., pulpotomy, pulpectomy) in both primary and permanent teeth.
6	**Extraction:** A tooth is indicated for extraction because caries has destroyed most of the crown or because periodontal disease has progressed to the stage that the tooth is highly movable and nonfunctional. Teeth that need to be extracted due to prosthetic or orthodontic reasons are not included here.
7	Reserved code (if more information is needed)
8	Reserved code (if more information is needed)
9	Not recorded (excluded). Code '9' (unerupted tooth) is assigned to the tooth in the diagnosis of caries.

For example, for a sound permanent molar which may benefit from sealants, the examiner will say, "1-ALL-F," where 1 is the diagnostic code for sound, ALL indicates that the code applies to all surfaces, and F means that a pit and fissure sealant is indicated for the occlusal surface.

Special Consideration Regarding Needed Treatment

A tooth should receive a sealant or restoration (fillings, crowns, etc.) to treat primary and secondary caries, replace lost or fractured restorations, correct anomalies in tooth shape and color (as when severe fluorosis is present), in cases of trauma, and to replace poor fillings or sealants. However, examiners need to be realistic and avoid "ideal" treatment plans. The need for prostheses should be evaluated separately by the examiner and only in the adult cohort 35–44 years old. Examiners should use their own criteria and clinical standards to assess the level and complexity of needed treatment. Generally, treatment for aesthetic reasons should be avoided (except in cases of severe tooth malformation), as should implants and crowns/veneers over teeth with a change in color due to trauma. Orthodontic treatment is not indicated, nor are tooth spacers or any removable or fixed appliance.

CODING FOR PROSTHETIC STATUS:
Individual coding for the 35–44-year-old cohort.

Code	Criteria
0	No prosthesis present
1	One fixed bridge
2	More than one fixed bridge
3	Removable partial denture
4	Both bridge(s) and partial denture(s)
5	Full removable denture
9	Excluded (children)

CODING FOR PROSTHETIC NEED:
Individual coding for the 35–44-year-old cohort

Code	Criteria
0	No prosthesis needed
1	Prosthesis needed for one tooth replacement
2	Multiunit prosthesis (fixed or removable) needed
3	Full denture needed
9	Excluded (children)

CODING FOR URGENCY OF TREATMENT

Code	Criteria
0	No need for current treatment
1	Tooth cleaning and scaling needed
2	Low urgency: Restorations and crowns needed, but none of them require immediate attention (restricted to the most superficial dentine). Include any person needing prosthesis or crowns.
3	Advanced urgency: Deep enough restorations and crowns need attention right away (within 7–14 days) to avoid pulpar involvement or infection. Include any child with five or more teeth needing restorations.
4	High urgency: requires urgent care due to pain or infection. Include here any person in need of pulpar treatment or extraction.

Items to Be Included in Reports of Epidemiological Surveillance Activities

Most epidemiological surveillance activities associated with salt fluoridation programs include variations of open-mouth visual and tactile surveys, which dental health workers conduct to assess standard measurements of oral diseases and conditions of the mouth.[3] This section describes the minimum data items to be reported from any open-mouth survey associated with salt fluoridation surveillance activities.

Sampling

All surveys include some sort of sampling procedure, in which a representative sample of the population is selected to be examined. Any survey report should include:

a. Type of sampling probability or nonprobability.
b. If probability sampling was used, the report should explain how the final sample was attained (such as through stratified sampling or cluster sampling). It also is important to include if any weighting or sampling design effect was used in analyzing the data and to identify any computer software (e.g., SUDAAN) used.

[3]The methodology and steps in these surveys have been described in PAHO's Regional Oral Health Program's "Final Report to the W.K. Kellogg Foundation," Project #43225, Multi-Year Plan for Salt Fluoridation programs in the Region of the Americas (Belize, Bolivia, Dominican Republic, Honduras, Nicaragua, Panama, Venezuela), published in Washington D.C. in 2000.

c. If nonprobability sampling was used (such as WHO's survey methodology, "pathfinder") the report should explain how the sample was attained and the criteria used to select geographical sites. Also, since many surveys of the pathfinder type include some randomness in the selection of sample units after the geographical sites have been selected, the report should describe these selection processes.

Calibration

Oral health surveys are conducted by examiners who apply specific diagnostic criteria and coding for each oral condition being examined. To obtain useful information, the diagnostic criteria and coding must be applied accurately and consistently across all examinees. Examiners and recorders learn these criteria during calibration exercises. Usually, these exercises take place immediately before data collection begins. Calibration of examiners and recorders includes discussion of the diagnostic criteria and coding, procedures for examination and recording, and duplicate clinical examinations of patients to test examiner reliability. Discrepancies in the application of diagnostic criteria during the clinical examinations are discussed and corrected. In most cases, examiners are considered "calibrated" when they obtain Kappa indicators greater than 0.60. (See "Calculation of Kappa [κ] and Percent Agreement [PA]" at the end of this protocol.)

Oral health survey reports should include a description of the calibration activities. Among items to include are:

a. How the calibration process was carried out.
b. How many examiners and recorders were included.
c. The coding for each oral condition that was examined.
d. The overall percent agreement and kappa for intraexaminer and interexaminer reliability.

Reliability

All examiners should demonstrate that they can apply diagnostic criteria accurately and consistently. Reliability has two dimensions: how reliable the examiners are individually (intraexaminer reliability) and how reliable they are among themselves (interexaminer reliability). The best technique for measuring reliability is to perform duplicate examinations during the calibration process. Duplicate examinations by the same examiner measure the reliability of that particular examiner. Duplicate exams by any two examiners measure interexaminer reliability. Two indices of reliability used extensively in oral health surveys are the percent agreement (PA) and Cohen's kappa (κ) and percent agreement (PA). (See Calculation of Kappa (κ) and Percent Agreement (PA) at the end of this protocol for formulas and an annotated example.)

Oral health survey reports should include the following information regarding reliability:

- Interexaminer and intraexaminer reliability scores using both kappa and percent agreement, for all variables.
- Interexaminer and intraexaminer reliability should be calculated for all possible examiners. However, when reporting reliability, all duplicate examination results across all examiners should be pooled and an overall measure of interexaminer and intraexaminer reliability should be reported. (See "Overall Reliability Estimates" at the end of this protocol.)

Data

Oral health survey reports should include tables providing data in the following areas:

Demographics

1. Distribution (number, percent in sample, and percent in the population) by sex, race, age, and geographical site/unit (according to sampling). To avoid crowding, these should be stand-alone tables. All tables should include totals at the bottom.

Disease Prevalence

Caries Prevalence and Severity

a. Age-specific proportion of persons with untreated decay or caries-free:
   - percent of caries-free persons in primary or permanent dentitions, and

- percent of persons with untreated decay in permanent and both dentitions.

b. Age-specific means and standard deviations (standard errors for probability sample surveys) for the following selected indicators of caries prevalence:
   - df-T (number of decayed and filled teeth in primary dentition)
   - DMF-T (number of decayed, missing, and filled teeth in permanent dentition)
   - df-t + DMF-T (total caries experience in both dentitions)
   - d-T + D-T (untreated decay in both dentitions)

   If the survey collected tooth surface information, a second table with the corresponding indicators should be included.

c. Age-specific contribution of the following components to DMF-T among those with DMF-T > 0
   - Percent D/DMF-T (Percent of decayed teeth within DMF-T)
   - Percent M/DMF-T (Percent of missing teeth within DMF-T)
   - Percent F/DMF-T (Percent of filled teeth within DMF-T)

d. Degree of caries experience in the permanent dentition, which is obtained by classifying the entire sample into four categories according to the individual DMF-T, as follows:
   1) DMF-T = 0
   2) DMF-T between 1 and 3.0 included
   3) DMF-T between 3.1 and 6.0 included
   4) DMF-T greater than 6.0

Other Oral Conditions

Age-specific tables should be generated for other conditions included in the survey. For example, if the survey obtained data for the presence of fluorosis or sealants, these variables need to be described for each age group and also after stratification by geographical site, sex, and race, if appropriate. It should be stressed that for conditions reported as a dichotomy (yes/no), the sample percentage for either "yes" or "no" category should be included in the table. If the condition has been reported as a category with many levels (polychotomy), e.g., Dean's Index of dental fluorosis, then the table should include the number and the percent for each category. Finally, if the condition is measured as a continuous variable (e.g., caries prevalence indices), then the table should include means, standard deviations, and standard errors in case of probability estimates.

Formatting Requirements

The following guidelines apply when preparing any table:

a. All tables should be stand-alone and self-explanatory. Titles should include information on four categories: person (population/sample), place, time (year), and statistic(s) included in the table.
b. Labels in tables should be clear and concise.
c. Titles should be consistent across all tables.
d. Use periods (.), not commas (,), to express decimals. Use commas (,), not periods (.), to express thousands.
e. For statistics such as means, standard deviations, and standard errors, values should be rounded upward to two decimal digits. For percentages use only one decimal digit. Integers should not be reported with decimal digits.
f. Do not calculate statistics for cells that have fewer than 30 persons. Be aware that some age groups will end up with fewer than 30 persons after stratification by variables such as sex and race. Exceptions to the 30-persons rule are those cases where the overall statistic has been computed based on more than 30 persons, but the number diminishes when the statistic is broken down (not stratified) by its constituent elements.
g. Include totals and subtotals in each table. Be sure that all subtotals add up to the total.
h. Any unusual element in the table, such as missing data, should be explained using a footnote. Also use footnotes to give the meaning of unusual abbreviations (such as "m.d." for "missing data;" "n.c." for "not calculated,") or symbols such as hyphens.
i. Charts and graphs are excellent media to show differences and trends. In oral health survey reports, charts and graphs can be included in addition to but not as substitutes for tabulated data.

Sample Data-Entry Form Used to Survey Schoolchildren

Duplicate	Update	Date	Examiner	Recorder
Strata		School	Grade	ID
Gender	Race	Date of birth		Age

Fluorosis	13:	12:	11:	21:	22:

	Mesial	Occlusal	Distal	Buccal	Lingual/buccal	Treatment
UR17						
UR16						
UR15						
UR14						
UR13						
UR12						
UR11						
UL21						
UL22						
UL23						
UL24						
UL25						
UL26						
UL27						
LL37						
LL36						
LL35						
LL34						
LL33						
LL32						
LL31						
LR41						
LR42						
LR43						
LR44						
LL45						
LR46						
LR47						

Prosthetic status	Prosthetic need	Treatment urgency

Calculation of Kappa (κ) and Percent Agreement (PA)

The following table will be used to describe the two most widely used measures of agreement for categorical variables used in oral health surveys. It shows all possible combinations in a set of paired measurements, using a three-level variable.

		First Measurement			
		1	2	3	$p_{i.}$
Second Measurement	1	a_{11}	a_{12}	a_{13}	$a_{1.}$
	2	a_{21}	a_{22}	a_{23}	$a_{2.}$
	3	a_{31}	a_{32}	a_{33}	$a_{3.}$
$p_{.i}$		$a_{.1}$	$a_{.2}$	$a_{.3}$	N

The first index, and the simplest one, is intuitively derived. Since all members of the diagonal of the table (a_{ii}) represent agreement between the two measurements, an index of agreement can be derived calculating their proportion over all possible pairs of measurements (N). This index is called *percent agreement* (Po) which is expressed as:

$$Po = \frac{1}{N}\sum a_{ii}$$

Unfortunately, some agreement is expected to occur by chance. The percent agreement expected by chance (Pe) is calculated by adding up the expected values for each cell in the diagonal of the table. Expected values are calculated using the distribution in the margins of the table (p_{ii}). Therefore:

$$Pe = \frac{1}{N}\left(\sum \frac{a_{i.}\,a_{.i}}{N}\right)$$

Cohen (1960) included these two terms in a proportion that estimates the agreement beyond chance. Cohen called his index kappa (κ) and defined it as the proportion of the observed excess agreement beyond chance to the maximum possible excess agreement beyond chance:

$$\kappa = \frac{Po\,Pe}{1\,Pe}$$

The value of kappa ranges from $-1 \le K \le +1$. If observed agreement is greater than chance agreement, $K > 1$, if observed agreement is less than chance agreement, $K < 1$. The asymptotic large sample variance of kappa may be estimated from:

$$s.e.(\kappa) = \frac{1}{(1\,Pe)\sqrt{(N)}}\,Pe + Pe^2 \sum p_{i.}\,p_{.i}\;(p_{.i} + p_{i.})^{-1/2}$$

where $p_{i.}$ and $p_{.i}$ represent the row and column marginal proportions, respectively.

Landis and Koch have provided an arbitrary guide to qualitatively assess the value of kappa:

Kappa	Strength of Agreement
0	Poor
0.01–0.20	Slight
0.21–0.40	Fair
0.41–0.60	Moderate
0.61–0.80	Substantial
0.81–1.00	Almost perfect

The following is an example of the calculations of kappa and percent agreement for intraexaminer reliability. The procedures are equally applicable for calculation of interexaminer reliability.

During a recent oral health survey, data were collected for presence of dental injuries in the front teeth. One examiner performed visual evaluation of the four upper and lower anterior teeth and recorded their injury status using the following coding:

0 = No evidence of injury
1 = Clinical evidence of injury (fracture, decoloration, missing due to injury, etc.)
8 = Not applicable: primary tooth
8 = Not applicable: missing due to causes other than injuries

Six-hundred-and-seventy-two children were examined; duplicate examinations were performed on 57 children. The table below describes the distribution of the 57 pairs of examinations:

The table indicates that a total of 456 (57 x 8) comparisons were made across all duplicate examinations.

According to our formula, percent agreement (*Po*) will be:

$$Po = \frac{(359 + 10 + 66 + 16)}{456} = \frac{451}{456} = 0.989$$

Injuries		First examination				
	Coding	0	1	8	9	Totals
	0	359			2	361
	1	1	10		1	12
	8			66		66
	9	1			16	17
Second examination	Totals	361	10	66	19	456

and chance agreement (*Pe*) can be calculated using the values at the margins of the table ("totals"):

$$Pe = \frac{\frac{(361x361)}{456} + \frac{(10x12)}{456} + \frac{(66x66)}{456} + \frac{(17x19)}{456}}{456} = 0.6498$$

therefore, kappa will be equal to:

$$\kappa = \frac{0.9890.6498}{1\ 0.6498} = 0.969$$

Therefore, percent agreement is 98.9% and kappa is 0.97. (Note that percent agreement is always greater than kappa).

Overall Reliability Estimates

The preceding section describes the steps to calculate intraexaminer reliability using kappa and percent agreement. In the example included in that section, all possible pairwise comparisons were summarized into a contingency table from where kappa and Po were calculated. Final values were the estimates of reliability for the examiner. When the survey uses more than one examiner, it is possible to calculate an overall estimate of *intraexaminer* reliability by pooling the data from each examiner into one contingency table. You also can obtain rough estimates by averaging the kappa and Po values for each examiner, but this requires that all examiners perform proportionally equal number of duplicate examinations.

Obtaining overall estimates of *interexaminer* reliability follows the same steps. After constructing contingency tables for each combination of examiners, all data is pooled into an overall table, adding the cell values from each table.

For example, assume that the following sets of 2x2 tables display information on the presence of fluorosis (yes/no) in duplicate examinations carried out by three examiners (each pair of examiners performed exams in six children).

		Examiner 1		
		Yes	No	Total
Examiner 2	Yes	1	1	2
	No	0	4	4
	Total	1	5	6

		Examiner 1		
		Yes	No	Total
Examiner 3	Yes	1	0	1
	No	1	4	5
	Total	1	5	6

		Examiner 2		
		Yes	No	Total
Examiner 3	Yes	1	0	1
	No	0	5	5
	Total	1	5	6

You can then add the values in each cell of each table and summarize the total into an overall contingency table:

		Examiner		
		Yes	No	Total
Examiner	Yes	3	1	4
	No	1	13	14
	Total	4	14	18

From this overall table you can calculate kappa and Po as described in the section on "Calculation of Kappa (κ) and Percent Agreement (PA)".

2. DETERMINING FLUORIDE CONCENTRATION IN DRINKING WATER

This protocol is a systematic tool for oral health workers to collect data on water samples, as part of an effort to determine naturally occurring fluoride levels in drinking water in areas that will establish a salt fluoridation program. The first part lists data that must be obtained and must accompany each sample; the second lists steps that should be followed in the actual collection of samples.

Water Sample Identifying Data

Sequential number. A sequential identification number must be assigned to each sample, in case it is necessary to verify the samples or for other follow-up needs. The sequence number can be assigned according to the geographical zone where the sample was collected.

Source name. Identify the origin of the water distribution sample.

Location. Name the district, city, and community where the sample originated.

Zone. Indicate whether the area where the sample was collected is urban, peri-urban, or rural.

Coverage. Determine and indicate the approximate number of persons that use the water source.

Soil. Soil type can influence the amount of fluoride in water. State whether the soil is rocky, clayey, sandy, volcanic, etc.

Altitude above sea level. Because individual metabolism (and, thus, retention and excretion of fluoride) varies with altitude, it is necessary to include altitude above sea level at the site where the water was collected.

Reservoir systems. Materials used in reservoir systems can influence the concentration of fluoride. Indicate if collection tanks are made of concrete, clay or clay fiber, aluminum, or fiberglass. Also indicate the piping material used to transport the water. This is a reason to collect water samples at the source and at residences.

Temperature. Provide the temperature of the air where the sample was collected. The range recommended for optimal concentration of fluoride in a given population may vary according to ambient temperature.

Type of sources. Specify the type of water source, such as a river, lake, creek, well, spring, etc.

Date. Provide the date of collection. Fluoride concentration in water may vary according to the time of year.

Name of responsible party. Identify the person responsible for collecting and identifying the water samples.

Technique for Sample Collection

Use 125 ml plastic bottles or 50 ml plastic cylinders.

Wash the container three or four times with the same water that will be collected.

Let the water run up to the edge of the bottle mouth.

After the sample is taken, close the bottle tightly.

Immediately identify the bottle with a premade label, providing the information listed above.

3. DETERMINING URINARY FLUORIDE EXCRETION IN CHILDREN: TIME-CONTROLLED URINE SAMPLING

One-time (spot) samples of urine offer insufficient information on average daily fluoride intake. This information can best be obtained from samples collected over a 24-hour period. This may be possible with parental collaboration or from hospitalized children. If it is difficult to obtain parental collaboration for supervised collection of urine during the morning and afternoon, efforts should be made for supervised collection of urinary samples during preschool and school hours and for one overnight collection at home. The following procedure has been adapted from standard methods for urine sampling and analysis to determine fluoride intake, as used in milk fluoridation studies. The procedure permits collection of urine over a period of 14–18 hours in a 24-hours cycle, and provides sufficient information to estimate the total daily fluoride intake in children.

Protocol Requirements

Since children 3–5 years old may be attending kindergarten or elementary school, arrangements should be made with the school administration in communities where urine sampling will be conducted. Administration approval is essential to facilitate communication with parents and to ensure that teachers and staff collaborate in all required activities before and during the project.

A brief clear note explaining the purpose of the study should be prepared by the investigators and made available to the school nurse, so it can be sent to parents asking them to allow their children to participate. The nurse should be informed of the study objectives, implications, risks. and the time that each participanting child would have to devote to the project, so that she or he can answer any questions parents might have. Invitations should be sent to parents at least one week in advance of the date for sampling. Parents should be informed that the consent form will include all pertinent information to the study and that it will be necessary for them to sign it to give permission for their child to participate.

Institutional Review Boards (IRB) oversee the safety and rights of humans participating as research subjects. The consent form must explain the purpose of the sampling and activities to be conducted, benefits and risks of the study to subjects, and participation time in plain language that will be easily understood by an individual with limited education. The consent form must be approved by the local IRB or equivalent agency and must be signed by the parent or guardian of the participating child, as well as by the investigator and a witness. The date the agreement was signed should be recorded. The project director will keep original signed and dated consent forms with other project records. A copy of the consent form should be given to the parent of the participating child.

Parents should also be instructed that they will need to provide demographic information on their child and to indicate the type of foods eaten by the child the day before and on the day of sample collection. Additional information on use of products containing fluorides (such as toothpaste, tablets, drops or topical fluorides) should be collected by having parents complete simple questionnaire.

General Instructions

1. The day before urine collection starts, it is advisable to meet with the school nurse to finalize details and to identify classrooms that will be used and restroom facilities for boys and girls, and to discuss the necessary project flow. Any additional information on project specifics can be provided at this time. Parents should be reminded that urine collection will begin the following day and that they should record the foods (solids and liquids) eaten by the child the day before and the day of the sample collection. Parents should be contacted directly or a note may be sent home with the child.
2. A roster of participating children should be made and corresponding identification numbers assigned to each child.
3. On the day of the sampling, when the child needs to urinate he or she is asked to empty the bladder. The name of the child and the time are recorded. The urine is *not* collected. This procedure is followed with each participating child. Note: With some 3-year-old children it may be necessary to use pediatric urine collectors.
4. When each child returns to urinate, a container of approximately 135 ml is given for him or her to urinate in. The time of urination and the volume of urine are recorded. The urine is then transferred to a larger, graduated container. The procedure is repeated at each urination during the pre-set collection period, i.e., morning, or period A. When each child next needs to urinate, a container of about 135 ml capacity is given to him or her to urinate in. The time and volume of urine are recorded.
5. At the end of the first supervised pre-set collection period, the process is repeated. The time should be recorded for each child. If a child is unable to urinate during this second collection, the time of his or her last urination is recorded as the end of his or her collection period.
6. For each child, the time and volume of urine collected are recorded on the test tube's label, and the following information transferred to the recording form:
   a. Time of initial voiding of the bladder
   b. Time of last urine collection into the large container

Recording Form for Collection of Urinary Samples

					School:			Locality: Mean temperature:			Date:		
Children's Data:						Period A (Morning)		Period B (Noon and Afternoon)		Period C (Afternoon & evening)		Period D (Nocturnal)	
No.	ID	Age	Sex	Weight		Start	End	Start	End	Start	End	Start	End
					Time								
					Vol.								
					Time								
					Vol.								
					Time								
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					Time								
					Vol.								
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Source: Adapted from WHO Form No. 96391 (2).

c. Total volume of urine collected between the initial voiding and the end of collection period.

7. Thirty ml of urine from the large, graduated container are placed into a plastic test-tube, and a small thymol crystal is added as a preservative. The cap is secured and the sample stored in a cool place. If a refrigerator is not available, a portable cooler with ice cubes or dry ice may be used to maintain samples at a cool temperature and to transfer them to the laboratory for analysis.

Steps 5–7 are repeated in the afternoon (Period B on recording form). If parents have agreed to collaborate on supervised collection at home during the remainder of the afternoon and evening, the procedure should be carefully explained to them. A container with a label marked as Period C should be made available; parents will enter necessary information on the label. If a third collection period is not to be conducted, an overnight collection should be arranged. A separate container should be provided to parents for this collection. The container should have a label on which parents can record the time of last urination before the child goes to bed and the time of first urination in the morning.

If it is suspected that the child may urinate during the night without notifying the parent, it may be necessary to fit him or her with a pediatric urine collector. Parents should be instructed on their method of its use and reminded that these collectors are for single sample collections. The collected urine needs to be emptied into a larger container and the volume recorded. If the child is old enough to urinate directly into the large container, he or she should be asked to do so if urinating during the night. The total volume of urine since the last urination before going to bed is recorded on the large container label for Period D. Samples need to be kept cool.

The concentration of fluoride is determined in each sample collected from each child for each period. The recorded volume and concentration of each sample for each period are used to calculate urinary flow and fluoride excretion rates per hour, per period, and for 24 hours.

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The Regional Oral Health Program is one of the Pan American Health Organization's greatest success stories, and salt fluoridation programs are the cornerstone of that success. Dental caries has been one of the most prevalent diseases among children in Latin America and the Caribbean. But adding fluoride to salt for human consumption promises to reduce caries by as much as 84%, at an extraordinarily low cost—6 cents per person annually. And for every $1 spent on a salt fluoridation program, $250 will be saved in reducing the need for future dental treatment.

Promoting Oral Health: the Use of Salt Fluoridation to Prevent Dental Caries is the bible of salt fluoridation. The book's first part traces the history of salt fluoridation programs, beginning from the earliest attempts in Switzerland in the 1950s to more recent success stories in Europe and the Americas. The second section is a how-to treatise for planning, launching, running, monitoring, and evaluating salt fluoridation programs. The third section presents recommendations for launching a salt fluoridation program, blueprints for proposing and enacting salt fluoridation legislation, and detailed standardized research protocols and sample forms for conducting epidemiological research—all of them essential tools for policy makers, health planners, and health workers.

More and more countries are starting national salt fluoridation programs, and this book will provide a useful road map as they set out to improve the oral health of their children and adults.

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ISBN 92 75 [illegible]