Salt fluoridation

Clinical trials

FOR almost four decades flouridation of drinking-water has been regarded as the most effective single method of preventing dental caries on a mass scale. Salt fluoridation as an alternative method was suggested more than 30 years ago (22) and the successful use of salt enriched with iodine to prevent goitre has led to studies in several countries using fluoridated salt for the prevention of caries.

Fluoridated salt has been on sale in Switzerland since 1955, and by 1967 three-quarters of domestic salt sold in Switzerland was fluoridated at 90 mg of F- per kg salt. However, it is now accepted that the original estimates of salt intake, based on urinary output studies and used to calculate fluoride concentrations in salt, were too high and the ingestion of fluoride too low. In more recent investigations, the level of fluoride has been raised to 200, 250, and 350 mg of F- per kg salt. Despite the widespread use of fluoridated salt in Switzerland, its effectiveness cannot be easily measured since, in many Swiss communities, other preventive programmes, including topical fluoride therapy, have been introduced in addition to fluoridated salt. However, Marthaler et al. (8, 9) concluded that the cariespreventive effectiveness of 250 mg of F- per kg salt used in the Swiss canton of Vaud was greater than the reduction of approximately 25% observed following the addition of 90 mg of F- per kg salt in other Swiss cantons (6). New results, obtained after eight years in the Canton of Vaud (11) and after four years in the Canton of Glarus (7) suggest that fluoride added to salt is as effective as fluoride added to water when the fluoride intake is similar.

Toth (19) reported the effectiveness of 250 mg of F⁻ per kg salt in Hungary after 8 years of use. The results indicated a reduction of 39% in deft^a in 6-year old children in the test community, while caries experience increased by 7% in the control community children over the same period. After 10 years' exposure to salt fluoridation, Toth (20) observed that 5-6-year olds in the same test community had 2.8 deft, compared with 6.0 deft in the control community, and 1.4 deft in children of the same age living in an area with fluoridated water.

In 1964, a well planned study was initiated in four Colombian communities (see Table 7) (13). In the village of Montebello, sodium fluoride (NaF) was added to domestic salt (at 200 mg of F⁻ per kg), while in Armenia calcium fluoride (CaF₂) was added to domestic salt (at 200 mg of F⁻ per kg), and in San Pedro drinking-water was fluoridated at 1 mg of F-per litre, while Don Matias remained as the control community. At the end of the project, after 8 years, reductions in caries prevalence in 8-year old children were large in the three communities receiving fluoride in salt or water, and a small reduction was also observed in the control town. When all children aged 6-14 years were included in the data analysis, the reduction in DMFT between 1964 and 1972 was 50% in Montebello (NaF), 48% in Armenia (CaF₂), 60% in San Pedro (water fluoridation) and 5% in the control town of Don Matias. It should be noted that the baseline values for the 6-14-year age group were about 2 DMFT higher in Don Matias than in the three test communities

In summary, the caries-preventive effectiveness of fluoridated salt is impressive, although based on a small number of studies (compared with water fluoridation) over a maximum duration of ten years.

Mode of action

Marthaler et al. (10) observed substantial reductions in caries experience in teeth exposed only post-eruptively to fluoridated salt. This appears to indicate that a topical as well as a systemic action occurs.

a deft= decayed-extracted-filled (primary) teeth.

Table 7. Comparison of DMFT mean and percentage difference between the baseline figures (1964)

Age DMF % once DMF			Armenia		-	Montebello	•		Don Matias	38		San Pedro	
1964 1972 ence 1964 1973 ence 1964 1973 ence 1964 1973 ence 1964 1973 ence 1964 1964 1973 ence 1964 1964 1973 ence 1964 1973 ence 1964 1973 ence 1964 1964 1964 1964 1964 1973 <th< th=""><th>Age</th><th>Ō</th><th>AF</th><th>8</th><th>DA</th><th>F</th><th> %</th><th>Ď</th><th>A.P.</th><th> %</th><th>VO</th><th>ΛF</th><th>% Differ</th></th<>	Age	Ō	AF	8	DA	F	%	Ď	A.P.	%	VO	ΛF	% Differ
0.35 50.70 0.75 0 100.00 1.00 0.93 7.00 1.13 0.36 84.55 2.35 0.60 74.47 2.29 2.62 -14.41 2.40 1.43 61.45 3.80 1.05 72.37 4.33 3.75 13.39 3.75 2.05 61.02 3.86 1.86 51.81 5.31 5.15 3.01 4.66 2.47 56.66 5.33 2.23 58.16 6.96 6.91 0.72 6.21 3.97 49.93 7.08 3.63 48.73 9.93 10.13 -2.01 7.80 4.96 47.76 8.59 4.50 47.61 10.72 11.03 -2.89 9.48 7.33 40.36 10.54 5.38 48.95 13.08 14.26 -9.02 11.05 8.15 15.80 9.60 7.44 22.50 15.57 16.43 -5.52 12.89 3.48 48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65 <th>(years)</th> <th>1964</th> <th>1972</th> <th>ence</th> <th>1964</th> <th>1972</th> <th>ence.</th> <th>1964</th> <th>1972</th> <th>euce</th> <th>1964</th> <th>1972</th> <th>ence</th>	(years)	1964	1972	ence	1964	1972	ence.	1964	1972	euce	1964	1972	ence
0.36 84.55 2.35 0.60 74.47 2.29 2.62 -14.41 2.40 1.43 61.45 3.80 1.05 72.37 4.33 3.75 13.39 3.75 2.05 61.02 3.86 1.86 51.81 5.31 5.15 3.01 4.66 2.47 56.66 5.33 2.23 58.16 6.96 6.91 0.72 6.21 3.97 49.93 7.08 3.63 48.73 9.93 10.13 -2.01 7.80 4.96 47.76 8.59 4.50 47.61 10.72 11.03 -2.89 9.48 7.33 40.36 10.54 5.38 48.95 13.08 14.26 -9.02 11.05 8.15 15.80 9.60 7.44 22.50 15.57 16.43 -5.52 12.89 3.48 48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65	9	0.71	0.35	50.70	0.75	0	100.00	1.00	0.93	7.00	1.13	0.23	79.64
1.43 61.45 3.80 1.05 72.37 4.33 3.75 13.39 3.75 2.05 61.02 3.86 1.86 51.81 5.31 5.15 3.01 4.66 2.47 56.66 5.33 2.23 58.16 6.96 6.91 0.72 6.21 3.97 49.93 7.08 3.63 48.73 9.93 10.13 -2.01 7.80 4.96 47.76 8.59 4.50 47.61 10.72 11.03 -2.89 9.48 7.33 40.36 10.54 5.38 48.95 13.08 14.26 -9.02 11.05 8.15 15.80 9.60 7.44 22.50 15.57 16.43 -5.52 12.89 3.48 48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65	۰ ۲	233	0.36	84.55	2.35	09.0	74.47	2.29	2.62	-14.41	2.40	0.35	85.41
2.05 61.02 3.86 1.86 51.81 5.31 5.15 3.01 4.66 2.47 56.66 5.33 2.23 58.16 6.96 6.91 0.72 6.21 3.97 49.93 7.08 3.63 48.73 9.93 10.13 -2.01 7.80 4.96 47.76 8.59 4.50 47.61 10.72 11.03 -2.89 9.48 7.33 40.36 10.54 5.38 48.95 13.08 14.26 -9.02 11.05 8.15 15.80 9.60 7.44 22.50 15.57 16.43 -5.52 12.89 3.48 48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65	- α	3.71	1.43	61.45	3.80	1.05	72.37	4.33	3.75	13.39	3.75	0.83	77.86
247 56.66 5.33 2.23 58.16 6.96 6.91 0.72 6.21 3.97 49.93 7.08 3.63 48.73 9.93 10.13 -2.01 7.80 4.96 47.76 8.59 4.50 47.61 10.72 11.03 -2.89 9.48 7.33 40.36 10.54 5.38 48.95 13.08 14.26 -9.02 11.05 8.15 15.80 9.60 7.44 22.50 15.57 16.43 -5.52 12.89 3.48 48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65	oσ	5.76	2.05	61.02	3.86	1.86	51.81	5.31	5.15	3.01	4.66	1.59	65.88
3.97 49.93 7.08 3.63 48.73 9.93 10.13 -2.01 7.80 4.96 47.76 8.59 4.50 47.61 10.72 11.03 -2.89 9.48 7.33 40.36 10.54 5.38 48.95 13.08 14.26 -9.02 11.05 8.15 15.80 9.60 7.44 22.50 15.57 16.43 -5.52 12.89 3.48 48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65	10	5.70	2.47	56.66	5.33	2.23	58.16	96.9	6.91	0.72	6.21	2.91	53.14
4.96 47.76 8.59 4.50 47.61 10.72 11.03 -2.89 9.48 7.33 40.36 10.54 5.38 48.95 13.08 14.26 -9.02 11.05 8.15 15.80 9.60 7.44 22.50 15.57 16.43 -5.52 12.89 3.48 48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65	 -	9 73	3.97	49.93	7.08	3.63	48.73	9.93	10.13	-2.01	7.80	3.65	53.20
7.33 40.36 10.54 5.38 48.95 13.08 14.26 -9.02 11.05 8.15 15.80 9.60 7.44 22.50 15.57 16.43 -5.52 12.89 3.48 48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65	12	9 44	4.96	47.76	8.59	4.50	47.61	10.72	11.03	- 2.89	9.48	4.10	56.75
8.15 15.80 9.60 7.44 22.50 15.57 16.43 -5.52 12.89 3.48 48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65	<u>ا ت</u>	12.29	7.33	40.36	10.54	5.38	48.95	13.08	14.26	- 9.02	11.05	6.47	41.45
48.37 6.30 3.17 49.68 8.63 8.24 4.52 6.65	4	9.68	8.15	15.80	9.60	7.44	22.50	15.57	16.43	-5.52	12.89	7.23	43.91
	Total	6.74	3.48	48.37	6.30	3.17	49.68	8.63	8.24	4.52	6.65	2.66	00.09

Data from Mejia et al (13).

Logistics, implementation, and technical aspects

Up to the present time, salt fluoridation has been limited essentially to domestic salt and/or table salt. From the standpoint of public health, it would be preferable to fluoridate all types of salt intended for human consumption as this would reduce the variation of intake between subjects (3). According to Toth & Sugar (21), 3.34 g of domestic salt were ingested per person per day in Hungary. The amount used in the kitchen, but not ingested, was much higher—4.91 g/day, and a further 2.72 g were used for purposes other than the preparation of food. In addition to the large variation in salt intake, a further problem of salt fluoridation is the difficulty of controlling the distribution of various concentrations to accommodate varying suboptimal levels of fluoride that occur naturally in water supplies.

Changes in food consumption patterns should also be taken into account. The amount of fluoridated salt ingested may decrease with increasing consumption of processed foods if the processors do not use fluoridated salt. As processed foods and ready-to-eat meals are gaining in popularity, there is need to compensate for the corresponding reduction in fluoride ingestion from domestic salt. This may be achieved either through supplying fluoridated salt to sectors of the food industry or by increasing the fluoride content of domestic salt; to do either, it is essential to have a thorough knowledge of food consumption patterns.

In 1981, the Swiss Academy of Medical Sciences (1) recommended that fluoridated domestic salt should contain 250 mg of F⁻ per kg instead of only 90 mg. The Federal Office of Health has approved this recommendation, which, early in 1982, was forwarded to the Conference of Cantonal Health Directors. This conference decided the issue in late 1982. Since April 1983, fluoridated salt contains 250 mg of F⁻ per kg throughout Switzerland.

For Basle and the surrounding towns, the existing water fluoridation policy will be pursued. For the remaining population of Switzerland, the decision to raise the fluoride content of salt from 90 to 250 mg/kg provides optimal (or perhaps slightly suboptimal) fluoridation for 4.5 million people who traditionally have been users of iodized salt. Fluoridated salt was, and will be, available at the same price as other kinds of salt (with or without the addition of 15 mg of iodine per kg).

A number of factors have favoured the implementation of salt fluoridation in Switzerland. They include:

- decentralized and/or intermingled water supplies that pose a serious economic obstacle to water fluoridation;
- uniformly low water F⁻ levels throughout the country (except in Basle and a few villages);
- centralized salt production under state monopoly;
- public ownership of salt production plants;
- independence of cantons regarding salt trade up to 1974;
- low cost of salt fluoridation;
- success of iodization of salt since 1920;
- substantial research within the country;
- successful results in Colombia and Hungary and additional scientific information from Spain and Sweden.

Much information on the history and scientific background of salt fluoridation in Switzerland is available in a special publication comprising 12 papers (4). During the 20 years' experience of large-scale production of fluoridated salt in Switzerland, technical problems have been overcome. When sodium fluoride was first added to domestic salt, separation tended to occur, but this problem was solved by the addition of tricalcium phosphate (15).

This situation led to the application of the following principles and measures that support the iodization and fluoridation of salt in an optimum manner:

- iodide- and fluoride-free salt varieties are still available, so that use is not compulsory;
- the selling price for all salt, with and without additivies, is the same;
- a process for the production of homogeneous mixtures of kitchen salt with iodide and fluoride has been defined (16);
- -centralized production, control, and distribution.

In 1980, iodized salt accounted for 95% and fluoridated salt for 65% of the packaged salt turnover; for the latter, the percentage reached 70 during the summer of 1983.

Thus, salt fluoridation, as practised in Switzerland, offers a choice to the public where it is available at no additional expense.

The scientific basis and practical aspects of salt fluoridation are discussed in a recent paper by Marthaler (5).

Economic aspects

Production of salt with a fluoride content of 90-250 mg per kilo is relatively simple. Sodium or calcium fluoride can be mixed with a slightly moist salt, or mixed with a flow conditioner, such as tricalcium phosphate, and then mixed with dry salt. Using the price of sodium fluoride given in Table 8, US\$1.82 will buy enough sodium fluoride to treat 500 kg of salt at a concentration of 200 mg/kg. Production costs in Switzerland are less than one US cent per kg. It has been stated that the Finnish salt fluoridation programme raised the sale price of salt by 1.2 cents/kg, a cost that covered the fluoride material, personnel, and marketing (2). There are no other special costs of administration, supervision, or distribution with salt fluoridation except, perhaps, the indirect cost of educating the public to use it.

Table 8. Prices of fluoride compounds and available fluoride

	Sodium fluoride (NaF)	Sodium silicofluoride (Na ₂ SiF ₆)	Hydrofluosilicic acid (H ₂ SiF ₆)
Price per kg (US\$)ª	1.43-2.20	0.66-0.99	0.07–0.33 (bulk)
Available F (%)	45.3	60.7	0.18–1.32 (drum) 79.2

US prices in 1981.

Evaluation and safety

To date, salt fluoridation schemes have been confined to four countries. The use of salt as a vehicle for fluoride is attractive, but would benefit from further long-term studies.

Fluoride ingestion should be studied by monitoring urinary output.

An inherent difficulty resides in the fact that salt intake, per se, is a controversial issue. The medical profession in general recommends reduction of salt intake. Schlierf et al. (17) indicated that the 5.0 and 95.0 percentiles of salt intake were 4.6 and 19.4 g of salt per day, whereas recommended daily intakes are 5 g or less. These recommendations are likely to lead to a decrease in the consumption of domestic salt.

From the limited data available, it would appear that CaF₂

Source: US Public Health Service, Centers for Disease Control, Dental Disease Prevention Activity, June 1982.

and NaF in salt result in similar preventive effects. However, further investigation is needed to confirm or deny that claim.

Legal aspects

The main advantages of salt as a vehicle for fluorides are that it does not require a community water supply and it permits individuals to accept or reject it; non-fluoridated salt, like non-iodized salt, can be available to the population. The main disadvantages are that salt consumption is lowest when the need for fluorides is greatest—in the early years of life (14)— and the current view that a high salt intake may contribute to hypertension.

Among the countries that have used salt as a vehicle for fluorides are Colombia, Hungary, Mexico, and Switzerland. The experience has been longest and most widespread in Switzerland. The Swiss conditions for permitting the use of salt as a vehicle for fluorides are particularly favourable, perhaps even unique, but nevertheless the experience gained in Switzerland can be useful to other countries.

The cantons of Switzerland have the exclusive right to sell and tax salt. This monopoly flows from Article 31 of the federal constitution (18).

Since 1973 an intercantonal agreement on the sale of salt has been in effect under which the cantons have delegated the exercise of their rights in this sphere to the United Swiss Salt Works, 1977. It should be noted that the cantons are also responsible for most aspects of health services in Switzerland.

Not only the juridical situation but the conditions for the manufacture and distribution of salt are favourable for salt fluoridation in Switzerland. Central production, central supervision of production, equal retail prices for salt with and without additives, clear declaration of contents, and comprehensive information and motivation of distributors and consumers all favour fluoridation of table salt (18).

Until recently, most of the Swiss cantons have offered table salt for sale with 90 mg of fluoride per kg. (The city of Basle has fluoridated its drinking-water since 1962 and fluoridated salt is not sold there). Since 1968, the Canton of Vaud and, since 1974, the Canton of Glarus have fluoridated their salt more highly (250 mg/kg). On the basis of studies of the results of more highly fluoridated salt in these two cantons, the Swiss Academy of Medical Sciences and the Federal Office of Public Health have

recommended the higher level. Specifically, the recommendations of the Swiss Academy of Medical Sciences in April 1981 are that (1) fluoridated, packaged table salt throughout Switzerland should contain 250 mg of fluoride per kg; (2) fluoridation of the public water supply in Basle should be continued, and no fluoridated table salt should be offered for sale in the region served by this fluoridated water supply; (3) fluoride tablets should be used only if medically prescribed; (4) fluoride toothpastes and other tried and proven local fluoride applications should be recommended; and (5) supervision of the fluoride intake by the population should be continued (1). It is expected that the cantonal authorities will adopt these recommendations.

Thus, with the exception of Basle, where water fluoridation has proved satisfactory, the needs and conditions in Switzerland have favoured fluoridation of table salt. A survey of a representative sample of the Swiss population in 1978 showed that the public is well informed about the significance and effect of adding iodide and fluoride to table salt and supports these preventive measures (18).

In Mexico, regulations of 18 February 1981 on the iodization and fluoridation of salt require the Secretariat for Health and Welfare to verify that all salt intended for human consumption, except salt intended for export and for use in the food industry, is iodized and fluoridated in accordance with official Mexican standards. Iodized and fluoridated salt must be registered with the Secretariat for Health and Welfare. Importers of salt for human consumption are required to verify that the product meets Mexican standards for iodide and fluorides. Provisions concerning labelling are specified. The Mexican Secretariat for Health and Welfare is authorized to use non-fluoridated salt in regions where there are cases of fluorosis or where fluorides have been added to the water supply. Thus, Mexico mandates salt fluoridation where water fluoridation is not possible.^a

In 1979, the Pan American Health Organization considered the magnitude of the problem of dental caries and the lack of resources for dealing with it. Acting in response to documentation presented by the governments of Mexico and Colombia and on the basis of the results of a salt fluoridation project

^a PAN AMERICAN HEALTH ORGANIZATION. Reports of the Director: Quadrennial 1978-1981, Annual 1981. Washington, DC, 1982, p. 137 (Official document No. 183).

conducted by the University of Antioquia, in Colombia (in collaboration with the Pan American Health Organization and with the assistance of the US National Institute of Dental Research), the Pan American Health Organization adopted a resolution that Member Governments "conduct salt fluoridation programmes as a temporary alternative measure to complement water fluoridation". The resolution further recommends that the Director of the Pan American Health Organization promote the integration of oral health activities in programmes of primary health care and seek extrabudgetary funds to support these activities for oral health.

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^b PAN AMERICAN HEALTH ORGANIZATION. Resolution XXXIX. Salt fluoridation. In: 1980 Report of the Director. Washington, DC, 1980, pp. 136-7, note 44. (Official document No. 167).

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Dietary fluoride supplements—school water and milk fluoridation

Clinical trials

Tablets and drops

ABOUT 55 reports on the effectiveness of fluoride tablets or drops have appeared in the literature, although some of these are difficult to interpret because of the small size of the test group, the short experimental period, or inadequate reporting (10). The remaining investigations fall into two groups: first those where the fluoride supplements were given daily at home and were started before school age, and second, those where tablets have been distributed at school on school days only, usually without additional supplementation during holidays or before school age.

(a) Deciduous teeth

Summaries of 20 trials of the effect of fluoride tablets or drops on the primary dentition are recorded in Table 9. A cariespreventive effect was consistently observed (about 50-80%) in studies where the initial age was 2 years or younger.

(b) Permanent teeth

Summaries of 32 trials into the effect of fluoride tablets in preventing caries in the permanent dentition are given in Table

10. In only four studies were fluoride supplements taken from birth for at least 7 years; reductions ranged from 39 to 80%.

(c) Fluoride-vitamin combinations

The effectiveness of fluoride tablets and drops is neither enhanced nor reduced by their combination with vitamins. There would seem, therefore, to be little advantage in these combinations per se. However, they sometimes provide a convenient method for delivering both types of supplement. If both are recommended, parents are sometimes more motivated to give vitamins than fluoride supplements to children and thus a combination may encourage the use of fluoride supplements. In such cases, it is important to stress to parents that the need for fluoride goes on for much longer than the usual time that vitamins are given; parents should therefore continue to give fluoride supplements to their children after they stop giving them vitamin supplements.

School water fluoridation

Studies and programmes of school water fluoridation have been carried out only in the USA. After 12 years of school water fluoridation at 5.0 mg/litre—four and one half times the optimum level recommended for community fluoridation in the same geographic area—children at a school in Pennsylvania developed 40% fewer DMF surfaces than their baseline counterparts (29). The findings showed a differential effectiveness according to time of tooth eruption; earlier erupting teeth (incisors and first molars) that were already in place when the children began to attend school had 31% fewer DMF surfaces, whereas surfaces of later erupting teeth (canines, premolars and second molars) that received both topical and systemic exposure to the fluoridated water in school developed 57% fewer DMF surfaces. Both earlier and later erupting teeth showed greater effects in proximal surfaces. The rate of extractions per 100 teeth decreased by 65% during the 12-year period of the study. Moreover, no objectionable dental fluorosis resulted from the procedure.

Another study of school water fluoridation at 6.3 mg/litre showed that a concentration 7 times the recommended optimum for community fluoridation in a geographic area produced only marginally greater benefits than at 4.5 times the recommended concentration (23). Therefore, 4.5 times the optimum fluoride

Table 9. Caries-preventive effects of fluoride tablets or drops on deciduous teetharman

	L	Daily	Initial age of	No. of subjects	Duration of F	Caries reduction $(\%)^c$	o(%)	Statistical
Study	compound ^b	dosage (mg)	subjects (years)	group	(years)	deft	defs	finácce ^d
Arnold et al. (4)	NaF	0.5-1	Birth-6	121	1-12	Comparable		Z.
						to water F		
Pollack (46)	NaF+V	-	က	100	7	08		Z C
	NaF+V	-	4	111	7	20		œ Z
Ziempowicz-Głowaka (58)	T CZ	80	ю	139	7		5 6	တ
Litomska & Kominska (39)	Le Z	9.0	3.4	154	7	No significant		Z Z
	<u>;</u>	!				effect		
Kamocka et al. (33)	TeX	0.75	m	64	ო	0		SN
Kalindoka et al. (66)	Na N	0.75	4	79	ო	0		SN
Leonhardt (38)	NaF + V	+	m	Not known	7	38		æ
(20)	> \	- -	4	Not known	7	90		Z Z
(3C PC) le te nomen	> + 4eN	7.1	Birth-54	82	ო		83	တ
nemion et al. (27-20)	NaF + V	0.50	Birth-54	25	4		89	S
	NaF+V	0.5-1	Birth-51	99	2		99	S
Margolis et al. (40)	NaF+V	0.5-1	Birth	149	9-4	9/		တ
	NaF+V	0.5-1	4	77	0-5	59		SZ
Hoskava (30)	NaN	0.25-1	Prenatal	78	4	93		ဟ
	ZaL	0.25-1	Birth-1	151	4	54		S
Kailis et al. (32)	NaF	~.	Prenatal	20	9-4	82		တ ်
	NaF	~.	Birth	92	4-6	26		တ [်]
Stolte (54)	~	-	ო	130	က	-		œ Z

Prichard (47)	NaF	~	Prenatal	176	8-9 9	70		S
	NaF	~	Birth	282	8 9	40		S
Hamberg (21)	NaF+V	0.5	Birth	342	ო	57		Z Z
	(drops)							
	NaF+V	0.5	Birth	342	9	49		Z E
	(drops)							
Kraemer (34)	CaF	-	4	170	7	22		Z Z
	CaF,	-	വ	82	7	18		Z Z
Schützmannsky (50)	NaF	_	Prenatal	100	-	13		S
	NaF	0.25-1	Prenatal	9	တ	30		တ
	NaF	0.25-1	Birth	100	တ	14		S
Aasenden & Peebles (1)	NaF + V'	0.5–1	Birth	87	8-11		78	S
Fanning et al. (17)	NaF	Not	-	581	വ	33		Z E
Andersson & Grahnén (3)	NaF	0.25-0.5	-	127	59	31		S
Hennon et al. h (27)	NaF+V	0.5-1	_	4	Ω		47	S
	NaF + V	0.5	-	47	ω		37	တ
Granath et al. (19)	NaF	0.25-0.5	2	48	2-4		46 BL	SN
							51 AP	တ
	NaF	0.25-0.5	2-3	123	1-2		33 BL	NS
							1 AP	SN

Based on Driscoll (10) and Binder et al. (7).

b V-vitamins.

c Verteaming AP-approximal surfaces.
d S-statistically significant; NS-statistically non-significant; NR-no statistical test reported.
f S-statistically significant; NS-statistically non-significant; NR-no statistical test reported.
f A NaF V combination was given up to 3 years of age. Beyond this age, some children received NaF + V, while others received only NaF.
g Aged 8-10 years at examination.
f In area with 0.6-0.8 mg of F //litre in the water supply.

Table 10. Caries-preventive effects of fluoride tablets on permanent teetha

	lable 10. C	aries-preven	tive effects	s of fluoride	tablets on pe	Caries-preventive effects of fluoride tablets on permanent teeth*	•	
		:	Initial	No. of	Duration	Caries	ies	
	ŭ.	Daily dosage	age of subjects	subjects in F	of F intake	reduction (%)	(%) u	Statistical
Study	compound	(Bm)	(years)	group	(years)	DMFT	DMFS	significance ^c
Stones et al. (55)	NaF	1.5	6-14	125	2	0		NS
Bibby et al. (6)	NaF	-	5-14	133	-		Ē	Z Z
•	Nar	-	5-14	119	_		Tentative	ď
							finding: ''possible''	
Niendenthal (44)	NaF	19	6-7	251	က	22		S.
Wrzodek (56)	NaF	10	6-9	8 381	ო	21		æ
	NaF	10	6-9	13 585	4	22		ď
Arnold et al. (4)	NaF	0.5-1	Birth-6	121	1-15	Comparable		œ Z
						to water F		
Krusic (35)	CaF	Not known	8-15	480	1-3	70		æ Æ
Pollack (46)	NaF+V	-	6-7	300	7	38		Z Z
Ziemnowicz-Glowaka (58)	NaF	0.80	3-6	704	7		33	ဟ (
•	NaF	0.80	2 -6	204	ო		78	ဟ ်
Jez (31)	CaF_{2}	Not known	7-11	7 200	$2\frac{1}{2}$	0		Y Z
Krychalska-Karwan &	1						,	
Laskowa (36)	ZaFi	Not known	Grammar	134	4		ဂ	r Z
M:	N. 1	30.0	9 44:0	75	Œ	36		Z Z
Grissom et al. (42)	> 4 Z	10	11.9	178	7	3	34	S
Kamocka et al. (33)	ZaZ	0.75^{d}	ო	64	ო	17		SZ
	NaF	0.75^{d}	4	79	ო	9		ဟ :
Leonhardt (37)	NaF	-	9	398	4	35		Y :
•	NaF	-	7	429	က	25		Z Z
Hippchen (28)	Not known	-	9	200	ო	32		Y Z

Z Z	Z Z	2	Z	Z	N N	S	χ Σ	N N	S	Z Z	SN	S	S	တ	S	S	S	S	S	SN	S	S	S	S
25 27	84 (except	1st molar) 33 (1st molar)	(ist iiloidi)			23			47					30	27	88	8				40	8	78	29
			16	20	24		31	69	36	70	9	43	39					43	28	4				
4 9	က		4	9	7	7	က	ო	1 -8	7	-	თ	တ	ო	ო	7	8-11	8–14	7–10	3 <u>-</u> 6	<i>)</i> 2	ო	9	9
580 197	105		158	160	109	130	Not known	150	450	342	91	91	100	109	114	208	91	3 0 8 4	26	31	127	54	150	135
တ ဟ	5-7		7-9	7-9	7–9	8 9	9	ო	7	Birth	Prenatal	Prenatal	Birth	8-11	8 - 11	7	Birth	Birth-14	Birth	4	-	51/2	6-7	6-7
0.75^{d} 0.75^{d}	0.5-19		19	10	19	19		_	0.5-10	0.5	-	0.25_{-1}	0.25-1	19	10	-	0.5-1	0.25-1	0.5-1	0.5-1	0.25-0.5	19	١٥	2α
NaF NaF	NaF		NaF	NaF	NaF	APF	NaF	Not known	NaF	NaF + V	NaF	NaF	NaF	APF										APF
Schützmannsky (49)	Berner et al. (5)					De Paola & Lax (9)	Giradi-Vogt (18)	Stolte (54)	Marthaler (41)	Hamberg (21)	Schützmannsky (50)			Aasenden et al. (2)		Plasschaert and König (45)	Aasenden & Peebles (1)	Binder (7)	Margolis et al. (40)		Andersson & Grahnén (3)	Stephen & Campbell (52)	Driscoll et al. (12)	

^a Based on Driscoll (10) and Binder et al. (8).

b V_vitamins
 c S-statistically significant. NS-statistically non-significant; NR-no statistical test reported.
 d Tables given only on school days.
 e A NaF +V combination was given up to 3 years of age. Beyond this age, some children received NaF + V, while others received only NaF.
 f Aged 8-12 at examination.

concentration for community water fluoridation continues to be the recommended standard for school water fluoridation. No objectionable fluorosis resulted from consuming the higher concentration of fluoridated water at school.

Milk fluoridation

Both bovine and human milk contain low levels of fluoride—about 0.03 mg/ of F⁻ per litre (16). Because milk is recommended as a good food for infants and children, it was considered, over 20 years ago, to be a suitable vehicle for supplementing children's fluoride intake in areas with fluoride-deficient water supplies. Ericsson (15) showed that fluoride was absorbed in the gut just as readily from milk as from water, refuting the suggestions that the high calcium content of milk would render the fluoride unavailable. However, the binding of added fluoride to calcium or protein might reduce the topical fluoride effect in the mouth compared with fluoride in water (14).

Despite the potential promise of milk as a vehicle for fluoride supplementation, only a few human studies have explored its use and these have had few participants (48, 53, 57). Studies in Germany and Japan (8) and Hungary have also been reported. Although the results have been encouraging, more clinical data are needed before the fluoridation of milk can be recommended as a community caries-preventive measure.

Mode of action

The effectiveness of the ingestion of fluoride tablets during the prenatal period has been investigated in six trials. In all of these, the percentage of caries reduction was greater in the children whose mothers received fluoride tablets in pregnancy. But, in spite of this apparently greater benefit of prenatal fluoride, Hoskova (30) concluded that fluoride administration should begin as soon after birth as possible, attributing the greater benefit in the prenatal group to better home conditions. The study by Schützmannsky (50) suggested that a small extra benefit may be derived from prenatal fluoride ingestion, particularly with regard to the deciduous dentition. The topical effect of fluoride tablets on the deciduous dentition was investigated by Granath et al. (19), who suggested that, while buccolingual surfaces may benefit if the commencement age is over 2 years, the effect on approximal surfaces is very much less

than if fluoride tablets are given earlier. With respect to permanent teeth, Margolis et al. (40) found that children who started taking fluoride tablets at birth showed at 58% reduction in DFT, compared with only a 14% reduction in the group who started at the age of 4 years; this suggested that it is important to commence ingestion in the first few years of life, before the permanent teeth erupt.

The results of school water fluoridation trials suggest that teeth receiving both topical and systemic exposure are best protected.

Logistics, implementation, and technical aspects

There is no logistic problem in the production of fluoride tablets. A number of manufacturers have produced tablets containing 0.25 mg of F⁻ and they can be obtained in Australia. Europe, and the USA. There has been considerable discussion, however, as to the optimum dosage of fluoride tablets and drops—at least 18 different dosage regimes have been published.^a In recent years, there has been a trend towards reducing the dosage of daily fluoride supplement for young children in Australia and Scandinavia. In the USA, the dosage recommended has been reduced for children from birth to age 2 years. The recommended dosages for children three years and older have remained constant. The objective of any systemic fluoride administration is to obtain the maximum caries-preventive effect with a low risk of unacceptable enamel mottling. In the past, fluoride tablet dosages have been calculated on the basis of providing the same fluoride intake as that of people receiving optimally fluoridated drinking-water. However, a dosage of fluoride given at a particular time of day produces a physiologically different effect from water fluoridation where fluoride is taken on a number of occasions throughout the day. Most regimens give sliding scales of dosages depending on water fluoride levels—for example, the Council on Dental Therapeutics of the American Dental Association recommends the dosage schedule shown in Table 11 for dietary fluoride supplements.

With regard to school water fluoridation, all the factors

^a Rugg-Gunn, A. J. Published dosage regimes for dietary fluoride supplementations. Evidence to the British Dental Association Dental Health Committee, February 1980.

Age (years)	Concentration	on of fluoride in wa	ter (mg/litre):
	less than 0.3	0.3-0.7	greater than 0.7
Birth-2	0.25	0	0
2-3	0.50	0.25	0
3-13	1.00	0.50	0

Table 11. Dosage schedule (in mg of F⁻/day) for dietary fluoride supplements according to fluoride concentrations of drinking-water and

referred to in the community water fluoride section are pertinent, although of course the equipment and the problems of storing the fluoride compounds will be much smaller. One problem of school water fluoridation is that it is best suited for areas where uniformly low concentrations of fluoride occur in both school and home water supplies. If some students drink nearly optimal concentrations of fluoride at home and others only trace levels, an appropriate concentration in the school's water supply is difficult to determine.

With respect to the implementation of non-supervised dietary fluoride supplementation schemes, the major problem is that a high degree of motivation, dedication, and perseverance is required of both parents and children for a long period of time.

Lack of compliance with the recommended regimen for an adequate number of years is a major disadvantage of tablets as a community caries-preventive measure—even when they are subsidized or distributed free of charge. After 9 months, Smyth & Withnell (51) discontinued a programme in which subsidized fluoride tablets had been made available, because only 22% of 3500 English children accepted and entered the programme, and less than 70 children received the tablets regularly. Furthermore, regular users of fluoride tablets at home tend to exhibit favourable dental health behaviour in other respects.

Economic Aspects

In the USA in 1982, prices of fluoride tablets varied from as little as US\$2.00 to as high as US\$16.25 per 1000 tablets. On this basis, the annual cost of implementing a programme of providing fluoride tablets to school children would range from

^a American Dental Association, Council on Dental Therapeutics. *Pediatric dentistry*, 4: 289(1982).

US\$0.36 to US\$2.93 per child per year (based on 180 school days per year). It is obvious that the cost of the fluoride in the tablets is minimal; most of the cost is in the stamping of the fluoride tablets and in the packaging and promotion materials. Shipping to countries outside the USA would cost more. However, there is no reason why sodium fluoride tablets should not be manufactured inexpensively in the countries requiring them.

An acidulated phosphate fluoride (APF) tablet is also available in the USA. This tablet is more expensive than the sodium fluoride tablet and does not necessarily offer additional benefits. According to Newbrun (43), indirect costs, such as personnel time, distribution of supplies to classrooms, and supervision of the programme, may increase the costs of implementing any school-based or public programme of fluoride supplementation. Newbrun estimated that the total cost may vary from US\$0.50 to US\$5.00 per child per year.

Where fluoride supplements are prescribed individually by dentists, the cost of tablets is considerably more than when they are purchased in bulk and administered in supervised school programmes. In such supervised programmes, the teachers' supervising time is usually not included in the cost of the programme, though it is obvious that supervision still is a cost. The actual cost of supervision will vary greatly from one country to another, with different labour charges and cultures.

Evaluation and safety

Schemes like the unsupervised provision of fluoride tablets and, to a lesser extent, the sale of fluoridated milk, require a high degree of motivation on the part of the parents and children. They are more difficult to evaluate in terms of percentage caries reduction than is community water fluoridation. Fluoride tablet administration, for example, will be associated with greater awareness of good dental habits and probably with a higher social class grouping and with greater economic advantages than the averages for the whole population served by a community water fluoridation scheme.

One aspect of the evaluation of fluoride tablet or milk fluoridation schemes is the duration of any particular study. Very few fluoride tablet studies have reported results after ten years and only one fluoridated milk study has reported results after five years. Another aspect concerns the number of children involved in the study—for example, in the milk study referred to only 49 children remained in the test group after four years (53).

The organization required to mount a fluoride tablet scheme in a large community in Bermuda was considered by Weddup. b He reported a trial in which 11618 children (80% of the Bermuda child population) were involved. Fluoride tablets or drops were given to children aged 6 months to 12 years and a fluoride mouth rinse to children aged 12-14 years. Once parental consent had been received, fluoride supplements were distributed and two dental nurses were then responsible for maintaining regular supplies to parents, keeping them motivated, providing an oral hygiene programme. The total cost, including all running costs, of administering the programme was US\$12.00 per child per annum (based on 11000 children). The scheme was evaluated in three ways. First the caries rates were shown to have dropped (for 8-year-old children from 1.4 DMF teeth in 1978 to 0.25 in 1981). Secondly, urine samples were taken and analysed for fluoride content, as a measure of compliance with the programme. Thirdly, enamel biopsies were carried out on 109 children participating in the study.

Weddup concluded that the Bermuda scheme demonstrated the feasibility of a preventive programme using fluorides other than by water fluoridation. Difficulties were encountered not only with purchasing tablets/liquid from overseas in bulk, but also with storage owing to the high humidity in Bermuda.

Fluoride tablets are inherently less safe than water fluoridation because of the risk of a large number of tablets being consumed within a short period.

With regard to school water fluoridation and other school-based dietary fluoride supplementation schemes, it is necessary to try to evaluate whether the benefits persist after the children leave or graduate from school. Thus, the effectiveness of school water fluoridation, for example, cannot yet be compared with that of community water fluoridation.

Legal aspects

Ingestion of dietary fluoride supplements (tablets) probably prevents dental decay as effectively as water fluoridation,

^b WEDDUP, J. E. C. Experiences in Bermuda. Paper given at the FDI/WHO/Kellogg Foundation Conference, Vienna, October 1982.

provided the tablets are taken according to a prescribed regimen daily from birth to age 14 years (22). In some countries, fluoride tablets are available only on prescription from a physician or a dentist. In other countries, fluoride tablets are available on an over-the-counter basis. In Norway, in 1975, the Ministry of Social Affairs amended the regulations governing the procurement of pharmaceutical products and their supply by pharmacies so that sodium fluoride tablets containing up to 1 mg of fluorine per tablet, used for the prevention of dental caries, are not exempt from prescription requirements, provided they are accompained by approved directions for use.

A 1977 Order of the National Board of Health and Welfare in Sweden recommends that children receive fluoride tablets between the ages of six months and six years, except where the drinking-water contains more than 0.75 mg of F⁻ per litre, and that topical fluoride application should be avoided in the case of children under four years of age. Only solutions prepared in pharmacies are authorized for use as individual mouthwashes in the home, and the dispensing of soluble fluoride tablets to patients is prohibited.

Regulation of fluoride tablets often comes under the general authority to regulate drugs. In Canada, the Food and Drug Regulations prohibit the over-the-counter sale of a drug containing fluoride if the largest dosage would result in a daily intake of more than 1 mg of fluoride ion. In the USA, the Food and Drug Administration has banned the making of claims that dietary fluoride supplements for pregnant women are effective in reducing dental caries in the infant, since such benefits have not been firmly established (22).

Indications for use

Tablets

- (a) In areas where there are no central water supplies, where the fluoride concentrations of well-waters are low, and where parental motivation is very high.
- (b) As an interim measure in those communities with a central water system that have not yet implemented community water fluoridation.
- (c) In areas where a water fluoridation or salt fluoridation scheme cannot be implemented.
 - (d) In families where there is a high degree of mobility

involving frequent changes in the place of work and residence and where parents wish to ensure daily fluoride supplementation themselves.

School water fluoridation

- (a) In areas where there are no central water supplies and levels of natural fluoride in drinking water are uniformly low.
- (b) In areas where, for some reason, other home-or school-based fluoride procedures may be impracticable.

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Topical fluorides

THE methods of fluoride application discussed so far entail the ingestion of fluoride, although they undoubtedly have a local intra-oral anticariogenic effect as well. After swallowing, fluoride is rapidly absorbed into the body and is deposited in the developing bones and teeth of young children. The excess is excreted, largely in the urine. The fluoride deposited in developing teeth increases their post-eruptive resistance to decay. In contrast, topical fluorides are applied directly to erupted teeth, and exert their effect at or near the tooth surface. Those protective effects may vary, depending on the agent used, its concentration and frequency of application, etc. Topical fluorides may be self-applied or operator-applied. Generally, self-applied fluorides are less concentrated than operator-applied fluorides.

Toothpaste

Investigations into the effectiveness of adding fluoride to toothpaste have been carried out since 1945 and cover a wide range of active ingredients in various chemical combinations. Fluoride compounds that have been tested for caries-inhibitory properties when incorporated into a toothpaste include: sodium fluoride, acidulated phosphate fluoride, stannous fluoride, sodium monofluorophosphate, and amine fluoride. The results of 90 trials of some of these agents^a show that brushing with a

^a Tables summarizing these results and those of mouth-rinsing trials are available, on request, from Oral Health, World Health Organization, 1211 Geneva 27, Switzerland. Reference may also be made to Murray & Rugg-Gunn (17).

fluoride toothpaste will reduce the incidence of dental caries (the amount of tooth decay occurring during the 1-3 year period of the trial) by about 20-30% (9, 22). These studies show that, in those countries where the habit of tooth-brushing is widespread, toothpaste is a useful vehicle for applying fluoride to teeth. In many such countries, fluoride-containing toothpastes comprise 80-95% of all dentifrice sales. Thus, in these countries, providing a person brushes his/her teeth at all, he/she will almost certainly be receiving the benefit of a fluoride topically applied.

Topical fluorides—group-administered

Other methods of topical fluoride application that are self-applied but have to be supervised in groups, and are therefore usually incorporated into school-based programmes, are mouthrinsing, tooth-brushing with solutions and gels, and applying fluoride gels in custom-made dental trays.

Mouth-rinsing

The first trials of fluoride mouth rinses were carried out in Scandinavia. Since then results of clinical trials in at least 13 different countries have been reported. Many permutations and combinations of the concentration of fluoride in the solution, the type of fluoride compound used, and the frequency of application have been studied. Twenty-four studies lasting two years or more have been carried out. All these studies refer to the permanent dentition and most of them reported a reduction of 20-35% in caries increment.

Neutral sodium fluoride is the compound that has been most commonly tested, and because of its effectiveness, ease of formulation, low cost, ease of storage, and lack of objectionable taste or possible staining, it is the agent of choice. Effectiveness may increase slightly with frequency of rinsing, but substantial reductions are observed with weekly rinses. Fluoride concentrations between 200 and 1000 mg of F⁻ per litre have been shown to be effective. Fluoride mouth-rinsing is not recommended for preschool children because many of them cannot

^a See footnote on preceding page.

^b 0.5 g NaF per litre = 200 mg F⁻ per litre; 2 g NaF per litre = 900 mg F⁻ per litre.

control their natural swallowing reflex and the ingestion of the mouth rinse could lead to dental fluorosis in developing, permanent teeth (23). Mouth-rinsing with fluoride solutions has been found to be effective in both nonfluoridated and fluoridated areas.

Solutions and gels applied with a toothbrush

Studies of various regimens of tooth-brushing with concentrated solutions or gels of fluoride about five times a year show that this method reduces dental caries by about 25% (5, 11). However, the procedure requires large quantities of expensive supplies, necessitates rigorous supervision of participants, and, depending on the methods used, may produce large quantities of unhygienic waste.

Gel-trays

One study has shown that daily use by schoolchildren of concentrated fluoride gels in custom-made dental trays reduces the increments of dental caries in a community with a nonfluoridated water supply by 75-80% (6). However, the same regimen used 3 times a week by children living in an area with optimally fluoridated water supply produced only a modest additional reduction in dental decay (7). With this method of application, small amounts of fluoride in high concentration (5g/kg) can be held in intimate contact with the teeth without being diluted by saliva. However, the method demands much time and cooperation on the part of the participating children and requires a high level of supervision, besides being complex and prohibitively expensive for public health programmes. Further research is needed to improve this method by the use of less costly, preformed trays and reduced frequency of applications.

Topical fluorides—operator-administered

Topical fluorides, in high concentrations ranging from 10-23 g F⁻ per litre, have been applied topically by dentists or other health professionals since 1941. Four main types of preparation have been advocated: neutral sodium fluoride solutions, stannous fluoride solutions, acidulated phosphate fluoride (APF) agents,

and varnishes containing fluoride. These agents have most commonly been applied at 6-monthly or yearly intervals. Ripa (18) summarized the results of 35 studies of solutions of NaF, SnF_2 , and APF and demonstrated that these agents produced similar benefits (a reduction of 20-35% in caries increment). However, APF has several other advantages over SnF_2 for professional application. The agent is not irritating to the gingiva, does not discolour enamel or restorations, has an acceptable taste, and is stable when kept in a plastic container.

After applications of concentrated fluoride solutions and gels. much of the deposited fluoride leaches from the enamel (1, 20). To reduce this loss, fluoride has been incorporated into varnishes, which, by adhering to enamel for prolonged periods, increase the opportunity for mineral uptake by surface enamel. Two commercial products have been mainly studied: Duraphat, which contains sodium fluoride (22 g of F per litre) and Fluor-Protector, which contains an organic (amine) fluoride (7 g of F⁻ per litre). Both have been tested in several studies, most of which were done in Europe. The findings have varied considerably (4). Moreover, shortcomings in design or operation mar most of the studies. In short, although laboratory data tend to demonstrate the theoretical advantages of these products, the clinical data are less conclusive. At present, fluoride varnishes do not seem superior to other operator-applied fluoride agents (4, 18) although the study by Koch & Peterson (14) reported a 75% reduction in caries increment after one year, following the use of Duraphat fluoride varnish. The reduction was found to be equally great on occlusal, approximal, and free smooth surfaces.

Combinations of fluoride therapy

When reviewing the effectiveness of fluorides in caries prevention, the usual tendency is to evaluate each method or regimen separately. This may, in fact, be unrealistic because fluorides are frequently used in combination. For example, because fluoride toothpastes have been widely used in the USA for many years, nearly all recent studies of fluoride mouthrinsing in that country inherently evaluate the effects of mouthrinsing added to those obtained from the use of toothpastes. Conversely, studies of fluoride toothpastes conducted in Scandinavian countries have evaluated the additive effects of toothpastes and mouth rinses because most Scandinavian children participate in school-based fluoride mouth-rinsing

programmes. A number of investigators, however, have studied the effects of combinations of topical fluoride therapy, including combinations of fluoride toothpaste with mouth rinses and topical gel applications (see, for example, ref. 2, 15, 16, 21). The combination of APF gel self-application and NaF fluoriderinsing has also been tested (10). Broadly speaking, it would appear that combinations of different forms of fluoride therapy increase the preventive effect, but the benefit is less than the sum of the effects of the individual methods. This is a most important point because, if it is true, it gives rise to the "law of diminishing returns" and brings into question the cost-effectiveness of using more than one type of topical fluoride agent as a public health measure. In other words, it questions whether it represents a good use of the resources needed to implement the additional procedure. Of course, the combination effect may be important in the management of a small subgroup who are particularly caries susceptible, in which case the usual cost-effectiveness approach is less relevant.

A further question to be considered is the use of a combination of "systemic" and "topical" fluorides (3). Such use seems logical—for example, the use of fluoride toothpaste in a natural fluoride area—but it must be remembered that each of these agents can have both a topical and a systemic component. Thus, fluoridated water acts systemically in enabling fluoride to be incorporated into the enamel pre-eruptively, but the water also has a topical effect once the tooth has appeared in the oral cavity. Similarly, a fluoride toothpaste has an obvious topical role when it is being brushed on to the teeth, but if swallowed by very young children it may also have a systemic effect.

Bearing these considerations in mind, a number of broad principles emerge. In public health terms:

- (a) there is no justification for using more than one "systemic" measure at any one time;
- (b) if an optimal "systemic" measure is in operation, the additional use of one "topical" method will be beneficial;
- (c) wherever possible, when combinations of fluoride therapy are being considered, it is most economical to choose those that are self-administered or group-administered;
- (d) professionally applied fluorides used in addition to a systemic regimen are appropriate only for individuals who have been identified as high-risk subjects.

Mode of action

As would be expected, the major action of topical fluoride agents is on the enamel of the teeth erupted into the mouth. However, because of their high fluoride content, special attention needs to be paid to the possible ingestion of fluoride from topical fluoride agents. For example, most fluoride toothpastes contain 1–1.5 g of F⁻ per kg. Excessive ingestion of fluoride toothpaste daily in young children would certainly have a systemic effect, which might well lead to dental fluorosis. For this reason, children under 6 years of age should be supervised when they brush their teeth with a fluoride toothpaste, or should have their teeth brushed for them by an adult, to prevent ingestion of too much fluoride whilst their permanent teeth are developing. The amount of fluoride toothpaste used for brushing a small child's teeth should be restricted in size to that of a small pea.

Similarly, mouth-rinsing with fluoride solutions is not recommended for children under 5 years of age because studies have shown that some preschool children lack the ability to control their natural swallowing reflex (8, 23) and might

regularly ingest too much fluoride.

Logistics, implementation, and technical aspects

In many developed countries, the logistics and implementation of the use of fluoride toothpaste is straightforward because almost all manufacturers have taken the decision to add fluoride to their product. Thus, in the United Kingdom and a number of other European countries, it may be difficult to buy a non-fluoride toothpaste. Moreover, a major effort has been made, by advertising and promotion, to persuade a greater proportion of the population to brush their teeth with toothpaste (necessarily almost always a fluoride toothpaste) regularly at least once a day.

The use of fluoride mouth rinses, although they are self-applied, requires more support for its implementation. Almost all fluoride mouth-rinsing programmes are school based and children enrolled in these programmes must be supervised by personnel who have received appropriate training, such as teachers, nurses, teachers' aides, or volunteers. The mouth rinses are usually measured accurately into paper cups, which are

disposed of after use. Some programmes use plastic cups that are washed and reused.

Other group-administered schemes, such as the application of solutions or gels by brushes or mouthpieces, require more logistic and technical support and demand much time and cooperation from the participating children.

The application of topical fluorides by dental personnel, in a dental surgery, creates a further complication in terms of logistics and implementation. From a technical point of view, dental research workers and dental manufacturing companies have constantly improved the topical fluoride agents available, making them more stable and palatable and easier to apply. The requirement of a one-to-one relation between the provider of the service and the recipient makes the operator-applied schemes difficult to implement in areas with a shortage of dental personnel, and the method is expensive for public health programmes.

Economic aspects

Fluoride mouth-rinsing programmes are considered to be one of the most cost-effective methods of preventing caries in schoolchildren. The fact that neither dental professional help nor sophisticated equipment is required to conduct the procedure, makes fluoride mouth-rinsing an attractive school-based programme in both developed and developing countries.

Successful clinical trials have been conducted with sodium fluoride, stannous fluoride, and APF. Neutral sodium fluoride is the material of choice for school-based rinsing programmes because children prefer its taste to that of the other two compounds and because it can be easily mixed and prepared on the school premises, rather than in a commercial laboratory. This latter attribute helps to make sodium fluoride rinses cheaper than those with either stannous fluoride or APF, while the absence of objectionable taste aids its acceptance. Fluoride rinse materials vary greatly in price from different manufacturers. Currently quoted prices in the USA, for weekly sodium fluoride rinses on a public health basis, work out at a cost of US\$0.75 per child per school year, assuming a 10-ml rinse. This estimate includes paper cups, paper napkins, and other materials. These products may, of course, cost much more in a developing country; paper cups are probably more expensive or even unobtainable, though some substitute from locally available

material could usually be arranged. Plastic cups, for example, appear to be widely available these days and can be labelled with the child's name and used many times to save expense. When fluoride rinse material, plastic containers, and pumps are shipped from the USA to another country, the cost per child jumps from US\$0.75 to US\$3.50 because of shipping costs. Local administrators will need to consider carefully the cost of imported materials against locally produced supplies.

Fluoride dentifrices have contributed significantly to the reduction in the prevalance of dental caries in children and in adults over the last several decades. Even though the annual expected caries reduction has been reported to be only between 20 and 35%, the cumulative effect is a sizeable and significant one, and in many countries fluoride dentifrices are used almost exclusively. In the USA, fluoride dentifrice is a 675-700 million dollar industry (Wall Street Journal, 21 September 1981). In Canada, expenditures for fluoride dentifrices account for approximately 50-70 million US dollars (Stamm, J. W., personal communication, 1982).

Fluoride tooth-brushing programmes are quite popular in Scandinavian school systems. In the USA, however, very few states have supervised tooth-brushing with solutions and gels. Alabama has a pilot programme that includes 25 schools (Shory, N. L., personal communication, 1982) with enrolment of 5000 children. Tennessee has a programme in which over 40 000 students are enrolled using an APF solution/gel and the students participate in the brushing twice yearly (Collier, D. R., personal communication, 1982). A similar programme involving more than 81 000 children is in operation in Indiana (Gish, C. W., personal communication, 1982). The US\$1.73. US\$1.80. cost per student is annual US\$0.75 in Alabama, Tennessee, and Indiana, respectively (see Table 12).

Fluoride mouth-rinsing is now one of the most widespread and well accepted preventive dentistry practices in school communities. It is estimated that, in the USA, over 10 million children are now participating in fluoride rinse programmes in schools, most using a 2 g/litre neutral NaF solution on a weekly basis (Horowitz, A., personal communication, 1982).

Table 13 lists the costs in many states of the USA that have fluoride rinse programmes. This list is not exhaustive but does provide an example of relative costs. The major factor influencing cost per student per year is whether personnel costs are included. In some states (e.g., North Dakota), the fluoride

Table 12.	Estimated annua	l cost per pe	erson for t	ooth-brushing
with solu	itions and gels in	Alabama, Te	ennessee a	and Indiana

	Alabama Projections for pilot	Tennessee	Indiana
	programme 1982–83 school year	Actual figures for 1981–82	1981–82
Number of schools (classes)	25	(1605)	122*
Number of children	5 000	40117	81 472
Salary of personnel (US\$)	4814	53 900	10890
Cost of F agent (US\$)	960	6420	
Type of agent	APF	APF	APF
Method of use	Brush-on	Self-applied Brush on	Self-applied Brush on
Concentration of agent	2.2% F ion	2.2% F ion	1.23% APF paste
Frequency	2 × yearly	2 × yearly	1 × yearly
Other costs, including	, •	•	
supplies (US\$)	2 007	11 700 ^b	44 810°
Time required (hours)	NA	6420	NA
Per diem, mileage,			
telephone, etc. (US\$)	855	NA	4 620
Total cost (US\$)	8 637	72 020	60320
Cost/student/year (US\$)	1.73	1.80	0.75

a Indiana has 315 school corporations. The actual number of schools in each corporation ranges from 2-95.

Sources: Alabama - Dr N. L. Shory; Tennessee - Dr D. R. Collier: Indiana - Dr C. W. Gish.

products are provided to the school system at no cost and the school system purchases the paper products and donates the salary and supervision time of the personnel. In other states (e.g., Iowa), public health dental hygienists visit the schools and conduct the fluoride mouth-rinse programme in addition to other oral hygiene instruction. A fraction of the dental hygienists' time is allocated to the mouth-rinsing programme. In these cases, the costs are proportionately higher, e.g., US\$0.75 to US\$0.95 per student per year, whereas in other programmes the costs could be as low as US\$0.29 per student per year.

Personnel

A fluoride mouth-rinsing programme requires and administrator, either full-time or part-time. Usually, this administrator is a dentist or hygienist attached to a health department or school

^b Includes toothbrushes, paper products, and disposable garbage bags.

c Includes F products.

Table 13. Estimated annual cost per person of supervised mouth-rinsing programmes with sodium fluoride solution (2g/litre) in different states in the USA

State	Number of schools or classes	Number of children	Time spent (hours) ^g	Salaries (US\$) *	Frequency per year	Cost of rinse (US\$) #	Other costs (e.g., cups) *	Total cost (US\$)	Cost per student per year (US \$)
Alabama	198	70974	640	2300	33	4035	18456	27 791	0.39
Florida	439	151 599	ΑN	0	32	37 900	75 799	113699	0.75
Georgia	387	132 231	Ϋ́	Ϋ́Z	27	Ϋ́Z	Ϋ́	99173	0.75
Idaho	166	31 034	Ϋ́	30 000	30	3175	10407	45 582	1.40
Illinois	427	78822	1400	12000	36	7500	27 793	47 293	09.0
Indiana	63	49 605	Ϋ́Z	9099	36	22818	2814	32 237	0.65
New York	200	73 244	Ϋ́	Ϋ́	36	Ϋ́Z	Ϋ́	18268	0.70
owa	245	40318	۷	∀ Z		۷	Ϋ́	30146	0.75
Kansas	16	6015	Ϋ́	0	36	2700	400	3100	0.52
Kentucky	924	302 000	Ϋ́	Ϋ́	30	28 690	137410	166100	0.55
Maryland	20	8273	1172	0	30-36	Ą Z	A A	6 200	0.75
Michigan	161	32 500	Ϋ́	0	36	Υ Z	Ϋ́	24375	0.75
Missouri	526	94 000	26 080	0	30	7236	27 936		0.37
Montana	130	30 000	220	0	33	1650	18 000	19650	99.0
New Mexico	4	1160	Ϋ́	0	34	Υ Z	ΑΝ	844	0.72
N. Carolina	824	312000	Ϋ́	ΑN	34	178000	A A	178000 6	0.57
N. Dakota	20	8820	Ϋ́	0	36	390	2212	2602	0.29
Oregon	419	53620	Ϋ́	۷ Z	36	24 452 c	26 675	51 127	0.95
Tennessee	957	23 936	200	4200	36	2600	13720	20 520	98.0
Utah	114	31 000	1800	0	36	23 250	0	23 250	0.75
Virginia	99	20 000	Ϋ́	0	36	Υ Y	∀ Z	37 500	0.75

ANA = not available or not separately tabulated.
 \$78 000 State funds matched by \$100 000 local funds - programme coordinated by public health personnel and administered by school personnel.
 c Includes administrative costs.

system, though public health nurses are known to administer some programmes. The administrator's tasks are to:

- achieve the cooperation of school authorities;
- ensure that the legal formalities, which vary in different countries, are completed (for example, laws on obtaining the consent of each participant and for prescribing fluoride must be complied with);
- purchase materials and supplies;
- recruit and train rinse supervisors;
- maintain records of programme operation;
- evaluate the success of the programme.

The salary of the administrator may or may not be included in the cost of the programme. The administrator's salary is a true cost, however, regardless of whether it is specifically included in cost computations or not.

Supervision in a mouth-rinsing programme is a little more demanding than it is with a fluoride tablet programme, and is therefore likely to be more expensive. Per capita costs quoted for the USA do not include supervision because this is usually provided by teachers or unpaid volunteers. However, where supervision must be paid for directly, it is likely to be the most expensive part of a rinsing programme in many countries. In one Canadian study, for example, the rinsing materials cost \$0.47 per child per year. When supervision by dental hygienists, administrative and travel costs were included, this cost rose to \$1.34 per child, assuming that the rinsing procedure lasted five minutes. When the rinsing procedure was timed to last 15 minutes, the cost was US\$2.94 per child per year (12).

The "indirect costs" involved in supervision apply not only to supervising mouth-rinsing programmes but, in fact, to all aspects of dental care. For example, the time spent by politicians and administrators in connection with water fluoridation programmes, the hidden costs of personnel employed to add fluoride to salt, and the costs involved in parents taking their children to the dentist for professional topical fluoride treatment, should also be taken into account.

Administration

Mailing and telephoning are often required in obtaining consent, so is printing or photocopying. Costs will vary from one country to another depending on legal requirements and on customs.

There will be travel costs for the administrator and the rinse supervisors, and time needed to train and monitor the supervisors will incur extra expense.

Indirect costs

A fluoride mouth-rinsing programme will function well if it has the support of the school authorities, of other health professionals, and of parents and the public. Securing this support may take relatively little time and expense, but in some circumstances it can be time-consuming. The administrator may need to meet a number of times with school authorities to explain the necessity for, and the operation of, the rinsing procedure. Some teachers may resist such programmes and individual discussions may be needed in order to overcome their doubts. If merely one influential person in the community, such as a prominent physician, is opposed to the programme, a great deal of the administrator's time can be absorbed in countering this opposition.

Some degree of public education is required before a mouthrinsing programme can be started, and this process must be allowed for in the administrative costs. A printed note to parents may be enough to obtain a high degree of participation, but more extensive education may be necessary in many instances. Administrators need to know their communities well. Some expenditure on education before the programme begins may save considerable time and expense later. Annual education/proactivities are needed maintain improve motion to or participation.

Evaluation and safety

All topical fluoride schemes referred to in this section have been subjected to rigorous, controlled, double-blind clinical trials, carried out by different operators in many parts of the world. Thus, they have all been evaluated closely during the period of the trial and in some cases have been subjected to follow-up studies to determine the extent of the caries-preventive effect when the topical application has ceased. One limitation of fluoride rinses, and probably other group-administered and operator-applied methods, is that the topical benefits may last only as long as the rinsing or application continues (13).

There is no doubt that concentrated topical fluoride agents,

containing 12-23 g of F⁻ per litre, must be kept under strict professional control and the amount of the agent used for any one patient must be kept to a minimum if nausea and vomiting are to be avoided.

Even with fluoride toothpaste and fluoride mouth rinses, care must be taken with young children. As already noted, children under the age of 6 years should be supervised when brushing their teeth and the amount of toothpaste used restricted to the size of a small pea. Mouth rinses are not recommended for children under six years.

Legal aspects

In Denmark, toothpastes may be exempted from the provisions of a 1964 Order prohibiting the addition of fluoride compounds or fluoride-containing substances to food cosmetics. Applications for exemption must be submitted to the Ministry of the Interior and must be accompanied by the following details: the name and address of the manufacturer or importer, the name under which the toothpaste will be sold, the name and composition of the chemical compound used, the maximum and minimum content of fluoride compound in the toothpaste, the maximum and minimum content of water-soluble fluoride compounds in the toothpaste when fresh and after three and six months' storage, the anticipated action of the fluoride compound in preventing dental caries, the toxicity of the compound, the labelling to be used, and any other relevant information. The container must bear the statement that fluoride has been added. The therapeutic or prophylactic action of a fluoridated toothpaste must not be mentioned in advertisements. either directly or indirectly, although the National Health Service may waive this provision in special cases.

The Council of the European Communities has issued a Council Directive dated 27 July 1976 regulating cosmetic products, including products for the care of the teeth and the mouth. It specifies that the maximum authorized concentraion of fluoride compounds in the finished product is 0.15% (1.5g/kg). Similar provisions are contained in an Ordinance of 16 December 1977 issued by the Federal Republic of Germany.

In Italy, a 1979 Ministerial Decree "adapting Italian legislation to EEC directives relating to oral hygiene products" repealed the former legislation which required toothpastes containing more than 10 mg of fluoride per 100 g of toothpaste

to be registered as medical products. This Decree lists the fluoride salts authorized in toothpastes, mouth washes, and chewing-gum, together with the maximum permitted level of each salt and prohibits the use of fluorides other than those listed or at levels exceeding those specified unless they are registered as pharmaceutical products. Oral hygiene products containing fluoride salts at the specified levels may be sold over the counter. The name of the salt or salts used must be stated on the package.

In Norway, toothpastes containing fluoride are not subject to prescription and may be sold by retailers other than pharmacies. Such toothpastes are nevertheless considered to be pharmaceutical products and their manufacture must be licensed by the competent ministry.

South Africa exempts toothpaste containing fluorides in quantities not exceeding 1.5 g of fluoride ion per kg from the labelling requirement for fluorides and certain mixtures.

Similarly, in Tunisia an Order of the Minister of Public Health exempts all oral hygiene products containing fluoride compounds at levels not exceeding those specified from the requirements concerning poisons intended for use in human medicine.

In the USA, the Food and Drug Administration issued a Notice in May 1974 concerning the content of topical fluoride preparations, based on a recommendation made by its Dental Drug Products Advisory Committee. The Notice indicates the composition of aqueous solutions and gels for topical application that is considered "safe and effective".

Indications for use

- 1. Properly formulated fluoride toothpastes are suitable for use by everyone, whether in low or optimum fluoride areas.
- 2. For children under 6 years of age, brushing should be supervised and the amount of fluoride toothpaste used restricted to the size of a small pea.
- 3. School-based fluoride mouth-rinsing schemes are indicated mainly for areas where the fluoride content of the water supply is low, particularly when fluoride toothpaste is not widely available, but supervisory personnel must always be provided.
- 4. Professionally applied topical fluoride therapy is most appropriate for special subgroups—for example, children exhibit-

ing signs of high caries susceptibility and those with certain medical conditions.

5. Adults with xerostomia caused by therapeutic irradiation or by various medications should receive professionally applied topical fluorides regularly in addition to using fluoride preparations at home (19).

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Other considerations concerning the appropriate uses of fluoride

T has been suggested that fluorine should be recognized as an essential trace element or micronutrient. The special interest in this element and the enormous amount of research devoted to its biological functions have been occasioned mainly by the usefulness of fluorides in the prevention of dental caries.

The two other principal means of preventing dental caries are dietary control and oral hygiene. However, the role and applicability of these two measures in public health are connected with complex behavioural and cultural problems. For this reason, they are not conducive to a rapid improvement in dental health. On the other hand, the use of fluorides, or at least the adoption of comprehensive programmes in which fluorides have played an important part, has led to a remarkable and rapid decrease in caries prevalence (2).

Choice of fluoride vehicle

Before choosing an appropriate method for delivering systemic fluorides or for giving a combination of systemic and topical fluorides, an analysis of prevailing conditions must be made. Useful guidance on making such an analysis can be obtained from other WHO publications (16, 17). The following steps are necessary:

(a) Demographic analysis (total population, age-distribution,

geographic distribution, urban and rural population, school-age children, school attendance, etc.).

- (b) Epidemiological data on caries: Prevalence (very low, low, moderate, high, very high); incidence (increasing, stable, decreasing); types of caries attack (initial, primary, secondary, root caries). If no epidemiological data are available, a "pathfinder survey" should be conducted, including 6-, 12- and 15-year-olds.
- (c) Assessment of the fluoride content of water supplies. The basic information needed in the planning of any type of fluoridation programme is the level of fluoride in household water. An ion-selective fluoride electrode is a valuable tool for these measurements. The extent of water sampling required will depend on the size of the fluoridation programme being considered and the number of feasible sources. It is advisable to obtain a general picture of the fluoride levels in the water supplies in each county (or other administrative area of similar level) (9). More detailed sampling can be made by local authorities.
- (d) Assessment of the average daily intake of fluorides from sources other than household water (4). Usually the most important source of fluoride is drinking-water. However, in some areas, there may be other significant sources of fluoride, such as tea or sea-fish, which should also be taken into consideration when deciding on the need for systemic supplementation. In the USA, Singer & Ophaug (14) and Ophaug et al. (10, 11) have completed extensive analyses of the diet of children and adults by market-basket analyses in different geographical regions.
- (e) A survey of available manpower and financial resources. Several methods of fluoridation require highly qualified personnel and/or abundant financial resources. Therefore, attention should be paid to these factors when choosing procedures.

Other information useful for the planning and selection of appropriate methods of fluoridation includes:

- health care organization (public/private sectors)
- existence of well-baby clinics
- day-care organization for preschool children
- school system (public/private, attendance rate, and age ranges)
- transportation systems
- food consumption patterns, diets
- attitudes of the key professions to fluoridation
- attitudes of the public to fluoridation
- age of target group.

Once all this information has been obtained, the planner has a sound basis upon which to choose appropriate methods and procedures.

Involvement of health personnel in fluoridation programmes

A successful fluoridation programme needs the involvement of all health personnel. The role of dentists and other oral health personnel is naturally crucial, but in the introduction and practical implementation other health personnel will also have their part to play.

Physicians

By virtue of their educational background, physicians usually occupy the managerial and chief positions in care services, often including those concerned with oral care. Therefore, it is vitally important that physicians be kept well informed about the most recent developments in the use of fluorides. In the USA, the medical profession was involved early with water fluoridation and the American Medical Association has repeatedly published statements supporting fluoridation. Half of the American population is enjoying the benefits of water fluoridation. In the United Kingdom, the fluoridation of water supplies made some progress after the report of the Royal College of Physicians (13). In Scandinavian countries, the medical associations have been indifferent to fluoridation; indeed some prominent physicians have directly opposed it. In all Nordic countries the progress of systemic fluoridation has been fairly limited.

The medical curriculum and the continuing education of physicians should include courses in preventive dentistry, emphasizing the role of fluoride in the prevention of caries.

Dentists

Dentists should naturally play a central role in the prevention of dental diseases. To plan, implement and evaluate preventive programmes, including the utilization of systemic and topical fluorides, dentists need comprehensive public health training. The importance of basic dental education in the prevention of dental caries has been demonstrated in a comparative study of American and Swedish dental students (12). The students of a

Swedish dental school were more in favour of topical uses of fluoride and less in favour of water fluoridation than their American counterparts. The proportion of Swedish students who believed in the superior effectiveness of water fluoridation was smaller than that of the American students. The Swedish school also introduced instruction in preventive dentistry later than the American dental schools.

The situation calls for the continuing education of dentists in preventive dentistry, including the use of fluorides.

Nurses and auxiliary health personnel

When modern dental education was introduced in the USA in the middle of last century, it resulted in a partial separation of the dental profession from other health personnel. Consequently, other health personnel do not pay much attention to dental diseases. In Finland, for example, the infant mortality rate has dramatically decreased since 1945 through the efforts paediatricians, district nurses, and nurse-midwives. In the subsequent two decades, Finland achieved one of the lowest infant mortality rates in the world and the general health status improved rapidly. There was, however, one striking exception: the dental health status of small children was extremely poor. It took until the early seventies before dentists and other dental personnel began to be incorporated into the well-baby clinic team. At that time also, a short dental course was added to the basic training of nurses. Nurses and other primary health workers usually take care of the dietary and nutritional counselling of expectant parents and families with small children. Therefore, it is imperative that the basic facts about the utilization of dietary fluorides in the prevention of dental diseases should be included in the training of nurses and auxiliary health personnel.

Dental auxiliaries

The role of dental auxiliaries is central to the practical implementation of professionally applied fluorides. It should be remembered that individual applications performed by dental personnel are the most expensive methods of fluoride use. Therefore, these measures should be limited to high-risk groups only.

Justification for new preventive measures

In general, the main obstacles to the introduction of classical methods of prevention have been found to be lack of acceptance, technical problems, and high cost. Of these three, lack of acceptance tends to be the predominant factor in highly developed countries. In developing countries, high cost and technical difficulties are the most serious problems. In view of the great importance of preventive methods suitable for the populations of developing countries, the technical and financial problems involved in the introduction of any new measures should be carefully assessed.

However, before implementation can even be considered, there has to be a long period of search for new preventive methods, with research into their effectiveness in principle, their clinical effectiveness in the target population, the extent of the protective effect, and the absence of unwanted side-effects. These questions have a high priority and it is essential that they must be clarified before consideration is given to acceptance, technical problems, cost, and cost/benefit ratio.

Approaches to testing preventive measures

When the effects of fluoride-containing waters were first investigated half a century ago, an invaluable source of information was provided by large populations living under different conditions and drawn from many nations and a great diversity of races. At that time, caries activity in many of those populations was high and the progression of lesions was rapid. Hence, when water fluoridation was introduced its effectiveness was obvious, although advanced epidemiological methods were not yet in use. Epidemiological research into the effects of fluoride-bearing drinking-waters did not even, at that time, have the benefit of the principle of "blind" comparative trials. This important deficiency in research design was compensated later, however, by consistent supporting evidence, including "blind" studies (8).

Nowadays, new alternative preventive methods must be subjected to painstakingly careful experimental studies, and the design of experiments must take into account all the techniques available and all facts known to modern epidemiology. This means that, after completion of animal experiments, large-scale, long-term longitudinal clinical trials must be conducted and critically evaluated.

The impact of declining caries prevalence on clinical testing

One of the new facts that is important in carrying out longitudinal clinical testing is the decline of caries activity and prevalence in many developed countries over the last ten years. As a consequence, in a longitudinal study, over an observation period of, for example, two years, the caries increment may be less than half what would have been expected ten years ago.

A minimum value for "t" (Student's t test) is required in order to reach a certain level of significance. At a given inherent level of variation (due to biological variables, examiners' errors. chance variation, etc.), the magnitude of the t-value depends on the size of the sample (n) and the average increment, that is the number of lesions at the end of the observation period (x_2) minus the number at the beginning (x_1) . These remarks on differences in caries prevalence over time also apply to differences in the caries increments in a control (x_{co}) and an experimental group (x_{exp}) . Without significant differences in caries prevalence over time, one cannot expect to obtain significance regarding differences due to an experimental variable (5, 7). In practice, this means that under the low-increment conditions prevailing today, sample size must be larger and/or observation periods longer than in clinical trials ten years ago; moreover, it may be necessary to eliminate subjects with very low caries risk and increment, or to select a special high-risk population for the clinical trial (3, 6).

Future possibilities

It is clear that although much has been accomplished through the use of fluorides, their potential benefits are not being enjoyed to the full. Evidence gathered from clinical trials and experiments carried out in rodents show that much more complete protection can be achieved by ensuring that fluoride is available in low concentrations for protracted periods, particularly at times when teeth are likely to be under caries attack. It is becoming increasingly evident that the fluoride ion exerts its maximum protection when it is present continuously in the mouth, and that it probably confers its beneficial effect through enhancing or promoting the remineralization of early caries lesions, thereby rendering those sites that are normally most susceptible to caries attack highly resistant to subsequent assault.

In studies in rodents, a slow-release device that allows fluoride to be released at a steady rate for up to 18 hours was

sutured on to the cheeks of the animals. Preliminary results show that substantial levels of protection of the smooth and sulcal surfaces can be accomplished by the use of these devices. Indeed, the results compare more than favourably with those found in rats consuming fluoride in their drinking-water at a concentration of 10 mg/litre. Rats wearing the fluoride-releasing device had caries scores as much as 70% lower on smooth surfaces, and 40% on sulcal surfaces than did animals drinking water containing 10 mg of F- per litre. This device could have considerable use in a relatively small group of the population. For example, slow-release devices might be used in subjects who are particularly prone to dental decay, such as some of the handicapped and those whose salivary gland function is impaired through disease or irradiation. In addition, such devices could be incorporated in space maintainers on othodontic appliances, partial dentures, and even in crown and bridge work. A major disadvantage from a public health aspect, however, is clearly that a professional person is required to fit the device. However, if levels of protection against caries of 70-80% can be achieved, this might render the cost acceptable. However, the methodology is still in the experimental stage and no clinical trials have been carried out to show its practicability and range of effectiveness.

Advice to individuals

The scientific basis for the systematic ingestion of the optimum amount of fluorides is medically, dentally, ecologically, and economically sound. Despite this, world-wide controversy surrounds the fluoridation issue. In many industrialized countries, there appears to be a growing desire among many people to "go back to nature". This desire often leads to a demand for "pure" water, natural or biodynamic food, the application of soft technology, and environmental protection. Some of these ideas are certainly worth while and desirable and would also, in many instances, promote oral and dental health. However, in some instances this type of ideology has led individuals, families, and communities to follow certain extremely unbalanced diets. Some health risks have been identified, particularly in children. For example, in Finland, rickets was practically eradicated over a period of several decades thanks to proper supplementation with vitamins A and D. Only recently, however, physicians have detected clear cases of rickets in children of families following certain extreme diets. Usually, these families belong to the highest social group.

There is a need, in some developed countries, for an appreciation of the risks of this attitude in certain sections of the population. It is necessary to improve communication with individuals who hold extreme views on diet and personal freedom so that they fully appreciate the part fluorides can play in caries prevention and they can make their personal choice on reliable information.

Insights and guidelines

The beneficial effects of fluorides on dental health have been proved by extensive experimental, clinical, and epidemiological research. Yet these benefits have been extended to only a small minority of the world's population. A great majority of the people of the world still suffer from needless dental disease, dental pain, and dental disfigurement. This is despite the fact that fluorides confer not only health benefits but major economic benefits as well. Dental treatment averted saves money for individuals, families, and nations.

One may ask why this significant breakthrough in preventive dental care has benefited only a limited number of people. Is it because of lack of awareness of the facts? No—because information on community water fluoridation and other vehicles for the use of fluorides has been widely disseminated among the health professions. Is it because fluoridation is expensive? Not at all—the costs of water fluoridation are modest, in fact, extremely modest when compared with the costs of dental care. Is it because of technological barriers? Again no—where community water systems exist and water-treatment plants are adding many chemicals to ensure safe, wholesome, and high-quality water, the technical problems of correcting a fluoride-deficient system are easily solved.

The reason for the gap between knowledge and implementation after so many years lies in fear and ignorance on the part of the general public, fed by a false appeal to individual freedom. Yet the courts, which are charged with the protection of constitutional rights, have held unanimously that fluoridation of community water supplies is a legal and sound exercise of governmental power.

In a sense, the public may well ask, "If water fluoridation is so beneficial, why doesn't the government do something about it?" Such a question highlights the importance of legislation on fluoridation. While in some places fluoridation can be introduced under existing public health legislation, the controversy that has characterized this issue in the past makes it imperative for governments to pass legislation expressly setting forth official endorsement of fluoridation. Such legislation can also set standards for a safe, wholesome, and high-quality water supply, authorize action by health officials and operators of waterworks, and remove any lingering doubts and ambiguities about the propriety and legality of community water fluoridation and other fluoride programmes.

World Health Organization policy on fluorides

As early as 1958, the World Health Organization recognized the importance of fluoridation and established an Expert Committee on Water Fluoridation. In its first report (15), that Committee endorsed the fluoridation of drinking-water as a public health measure and recommended that, where this measure cannot be used, research into other vehicles and improved methods of local fluoride application should be encouraged.

In 1969, the Twenty-second World Health Assembly recommended that Member States introduce community water fluoridation and, where this is not practicable, study other methods of fluoridation to protect dental health. In 1974, the Executive Board of the World Health Organization requested that the Director-General develop a programme within WHO for the promotion of community water fluoridation and other approved methods of preventing dental caries. Noting that no nation can expect to solve the problem of dental caries solely by the provision of curative services, the Twenty-eighth World Health Assembly in 1975 approved the programme proposed by the Director-General and stressed the importance of optimizing the fluoride content of water supplies. In 1978, the Thirty-first World Health Assembly reaffirmed its support of fluoridation as safe, inexpensive, and effective, and urged Member States to consider fluoridation of public water supplies as part of their national plans for prevention and control of oral disease; and it suggested that, where community water fluoridation is not feasible, alternative methods of achieving optimum daily intake or application of fluorides should be envisaged. This repeated emphasis by WHO on community water fluoridation and on

other methods of using fluorides to prevent dental disease is an indication that there is not, and never has been, any question about desirable health policy in this area. The only question is how to implement it.

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Conclusions and Recommendations of the FDI/WHO/KELLOGG Foundation Conference on Fluorides, Vienna, 3-5 October 1982

- 1. The International Conference on Fluorides reviewed the findings of recent experimental, clinical, and epidemiological research on the use of fluorides in promoting dental health. While welcoming the reports of declining caries experience in many developed countries, it was greatly concerned about the sharp increase in dental caries in some developing countries. As there is no possibility of treating so many decayed teeth with the dental resources at present available in the developing countries, the only hope is to contain the caries problem by preventive measures.
- 2. The Conference agreed that community water fluoridation is an ideal public health measure for the prevention of dental caries in countries with well developed, centralized public water supplies. It was in agreement with the view of the FDI, WHO, and the medical and dental professions throughout the world that community water fluoridation is an effective, safe, and inexpensive preventive measure, which has the virtue of requiring no active compliance on the part of the persons benefited. The

Conference recommended that community water fluoridation be introduced and maintained wherever possible.

- 3. Unfortunately, the vast majority of the world's population live in rural and urban areas with few large water installations. In these situations, community water fluoridation is not feasible and alternative strategies need to be adopted. There is evidence from three long-term studies in both developing and industrialized countries that salt fluoridation may be nearly as effective as water fluoridation in reducing the incidence of dental caries. Consequently, the Conference stressed the need for more long-term field trials of salt fluoridation.
- 4. There is no justification for using more than one systemic fluoride measure at any one time.
- 5. Various topical fluoride methods, or combinations of such methods, may be beneficial in communities that have a source of systemic fluoride that is used widely.
- 6. Wherever possible, when combinations of fluoride therapy are considered, it is best to choose those that are self-administered or group-administered because they are less expensive.
- 7. Professionally applied fluorides are particularly appropriate for individuals who have been identified as at high risk of dental caries
- 8. The Conference was concerned about the problems of dental fluorosis in areas with high concentrations of fluoride in the public water supply and urged research to develop effective, simple, and economical defluoridation methods for water supplies of varying sizes. It recommended that, in children under the age of 6 years, brushing with a fluoride toothpaste should be supervised in order to prevent excessive ingestion. For similar reasons, fluoride mouth-rinsing should not be considered for children under 5 years.
- 9. Current knowledge of the effectiveness of various methods of using fluorides led the Conference to conclude that each country should review its own dental needs and take legislative action to adopt those methods of using fluorides that best suit its needs in different regions. In view of the proven value of fluorides in promoting dental health, their use should be extended without further delay to all populations throughout in the world.

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