

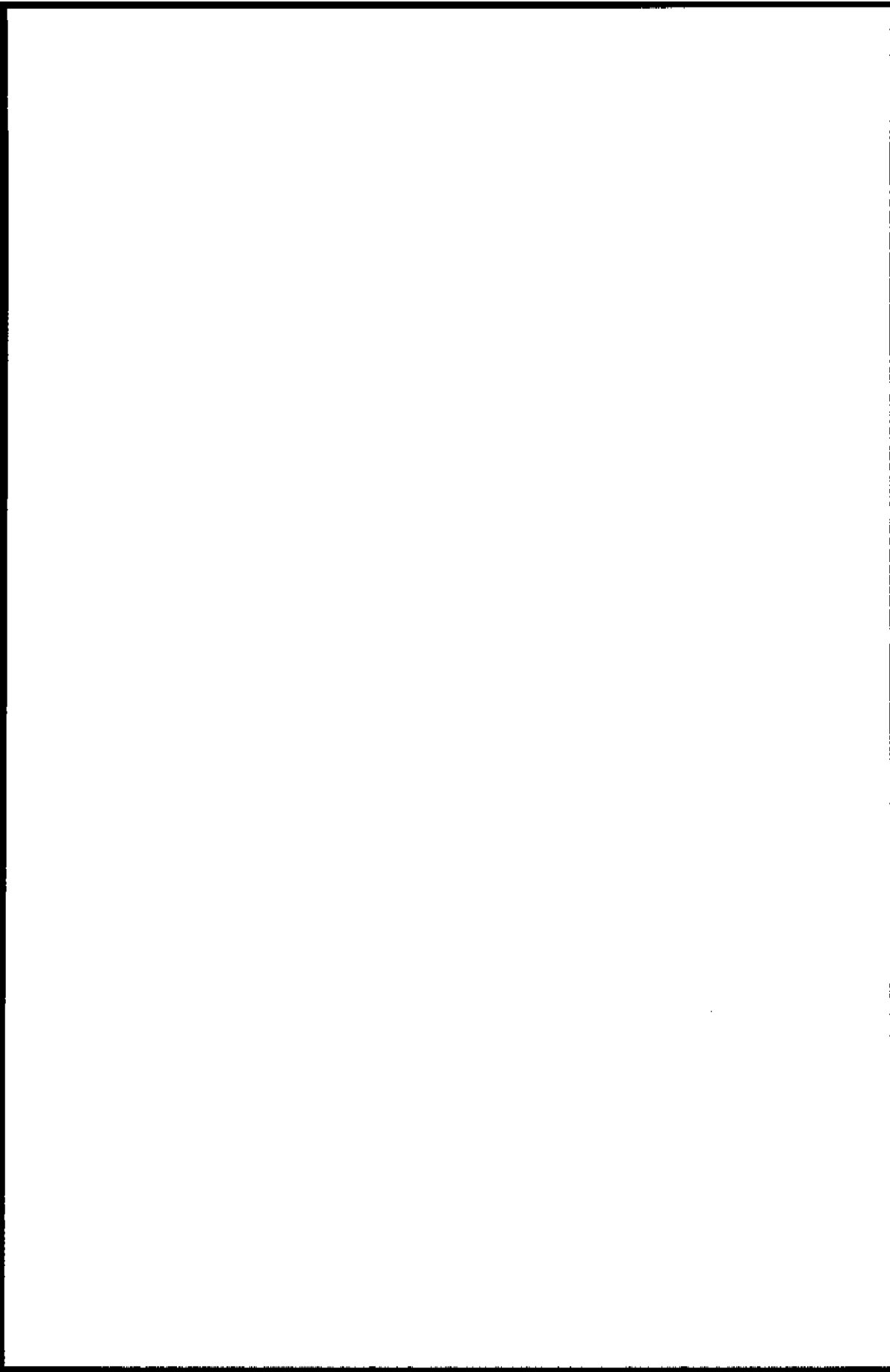
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FLUORIDE VARNISH

*for community-based
caries prevention
in children*



ORAL HEALTH
DIVISION OF NONCOMMUNICABLE DISEASES
WORLD HEALTH ORGANIZATION
GENEVA



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English only

**Fluoride varnish
for
community-based
caries prevention in children**

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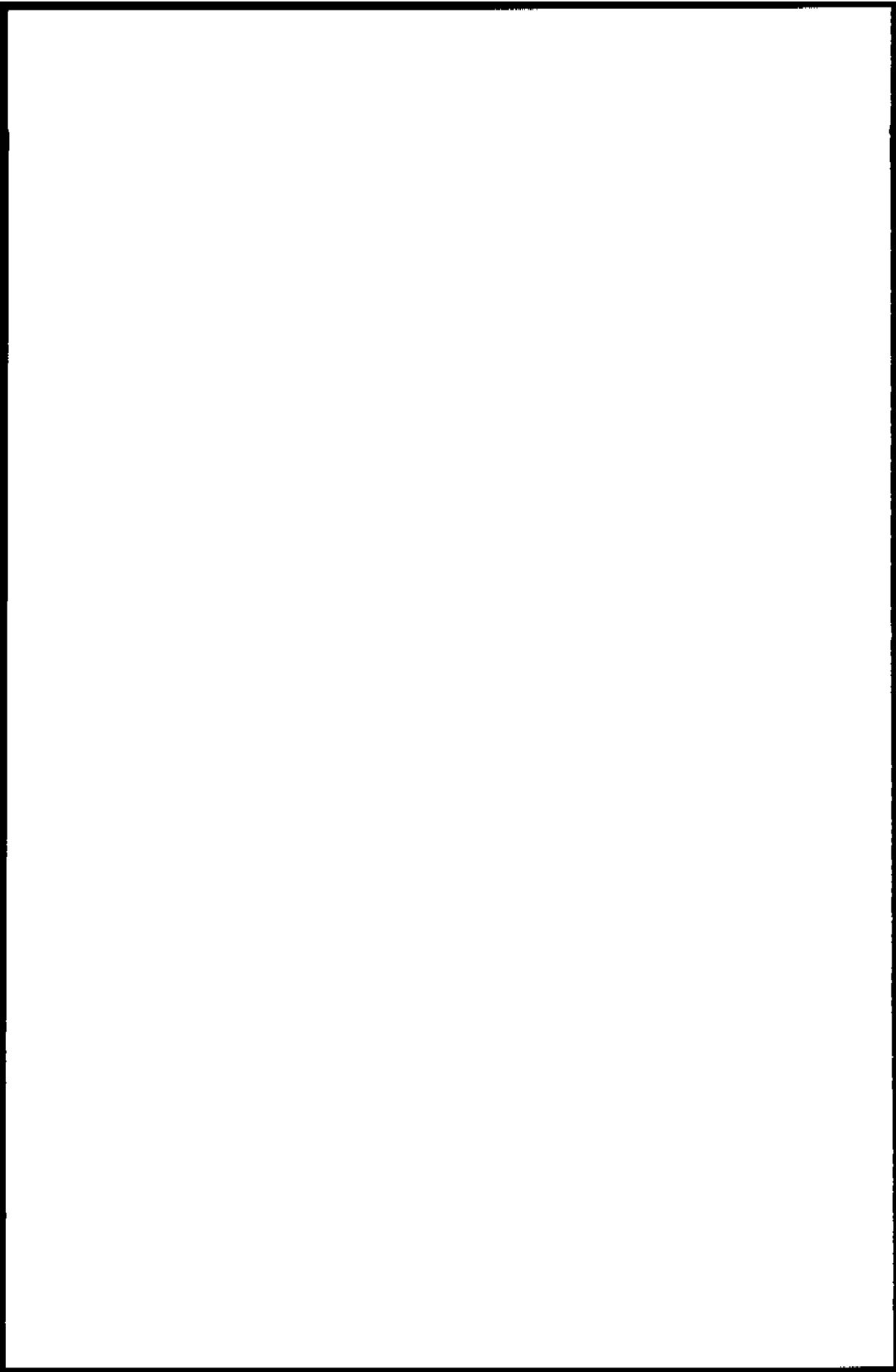
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Contents

| | |
|--|----|
| 1. Introduction | 1 |
| 2. Assessment of a fluoride preventive measure for community use | 3 |
| 2.1 Cariostatic mechanism and clinical effects | 3 |
| 2.2 Fluoride metabolism, side-effects and safety | 7 |
| 2.3 Recommendations for communities and individuals | 8 |
| 3. Guidelines for demonstration projects using fluoride varnish. | 9 |
| 3.1 Project planning and preparation of protocol | 9 |
| 3.2 Selection of study groups | 9 |
| 3.3 Training and calibration of examiners | 10 |
| 3.4 Approvals | 11 |
| 3.5 Patient consent | 11 |
| 3.6 Baseline examinations | 11 |
| 3.7 Follow up and final examinations | 12 |
| 3.8 Statistical Methods | 12 |
| 3.9 Evaluation of results | 12 |
| 3.10 Reporting | 12 |
| Annex 1 - Fluoride varnish application technique | 13 |
| References | 15 |

Abstract

This document reviews the development of fluoride varnishes; then compares the two types of varnishes available in terms of characteristics, viscosity, fluoride content, and solvents. A general overview of assessment of fluoride preventive measures for community use is given. The varnishes are compared with respect to fluoride dose and plasma concentrations - *Fluor protector* giving very low peaks, similar to those produced by fluoride toothpastes, compared with *Duraphat* that results in plasma peaks of 60 to 180 ng/ml. Recommendations for fluoride varnish use appropriate to high and low caries communities are then given. Guidelines for demonstration projects are provided. The Annex gives a step-by-step description and pictures of the varnish application technique.



1. Introduction

The purpose of this document is to give an overview of the clinical and health economic considerations relating to fluoride varnish use as a dental caries preventive method and is directed at general practitioners and oral health care auxiliaries, as well as health care planners. The guidelines provided are appropriate for populations with a community dental care infrastructure. In particular, this type of preventive agent is cost-effective for children with a high risk of caries, and for those where increases in caries levels in the primary dentition have been identified.

The practical and positive characteristics of fluoride varnishes include ease of use with respect to handling and application, acceptability to patients and an adequate safety level. In addition, the major clinical advantage of fluoride varnishes is their specific ability to adhere to tooth surfaces thereby prolonging fluoride exposure and uptake. During the time the varnish remains on the teeth, fluoride ions are released into the adjacent tooth surfaces and subsurfaces, and into the saliva and dental plaque of the oral cavity.

The use of fluoride varnishes for topical fluoride application therefore has been an important development in the field of preventive dentistry. Since their introduction, they have become a popular and efficient method and are used in many countries, particularly in Europe.

Development of Fluoride Varnishes

A fluoride dental varnish can be defined as a lacquer or liquid, made from a natural or synthetic base, in which fluoride salts are dissolved in a solvent such as ethanol. The varnish coats the tooth surfaces as a thin layer that hardens a few minutes after application.

The development of fluoride varnishes began in the 1960s following the observations of Mellberg et al. (1966) who found that considerable amounts of fluoride were released from enamel within the first 24 hours following the topical application of acidulated fluoride phosphate preparations. The efficiency of a topical fluoride application was found to be strongly related to the contact period with the enamel (Brudevold et al., 1967). Moreover, Richardson (1967) demonstrated that fluoride uptake in enamel was increased by prolonging the time interval between a fluoride application and the subsequent exposure of the enamel to saliva. He therefore suggested that after topical fluoride application, enamel should be coated with a water repellent agent to increase fluoride uptake. Meanwhile, Schmidt (1964) presented a new topical fluoride method using a varnish with a high fluoride concentration, *Duraphat* (Rhone-Poulenc Rorer, Rorer GmbH Köln, Germany) which had the ability to adhere to tooth surfaces in the presence of saliva. A second varnish system with a lower fluoride content, *Fluor Protector* (Vivadent, Schaan, Liechtenstein) was introduced about a decade later by Arends and Schuthof (1975).

Duraphat varnish consists of a natural resin (colophonium) base with 5 % sodium-fluoride (2.23 % F) dissolved in ethanol. *Fluor Protector* contains only 0.1 % F⁻ as difluorosilane dissolved in ethyl acetate and isoamylpropionate solution which has acidic properties. The difference in the solvents used in the two varnishes is important since they not only influence the adhesive character of the varnish, but also the diffusion of the fluoride ions within the biological apatites as the acidic polymer enhances diffusion of fluoride ions into enamel. Besides the fluoride concentration and the solvents, the two varnishes differ with respect to consistency, hardening time, colour, scent and taste (Table I). *Duraphat* is a yellow viscous lacquer supplied in 10 ml tubes or in 1.6 ml cartridges. It hardens after a few minutes on the tooth surface into a yellowish-brown coating. *Fluor Protector* is a colourless light-flowing liquid supplied in 1 ml ampoules, which hardens into a thin transparent coat. Both varnishes have a fruity scent with a banana-like flavour for *Duraphat* and a lemon-like flavour for *Fluor Protector* which make them reasonably acceptable to most patients, even small children. The application procedures are described in Annex 1, Fluoride Varnishes - Application Technique and need to be followed to achieve an optimal effect.

Table I - Fluoride varnish characteristics

| | <i>Duraphat</i> | <i>Fluor Protector</i> |
|-------------|----------------------------|----------------------------------|
| Colour | Yellow-brown | Transparent |
| Consistency | Viscous, slow flowing | Light-flowing liquid |
| Base | Natural resin; Colophonium | Synthetic; Polyurethane |
| Fluoride | NaF, 2.23 % F | Difluorosilane, 0.1% F |
| Solvents | Ethanol | Ethyl acetate; Isoamylpropionate |
| Smell | Fruit | Fruit |
| Flavour | Banana-like | Lemon-like |

2. Assessment of a fluoride preventive measure for community use

Factors that must be considered when choosing a preventive measure include, cariostatic mechanisms, clinical effects, safety, side effects, and cost.

2.1 Cariostatic mechanism and clinical effects

Topical application of concentrated fluoride solutions to teeth to prevent caries, started in the 1940s when Knutson and Armstrong (1943) conducted a series of clinical experiments using 2% neutral sodium fluoride solution. Numerous clinical studies thereafter, using different fluoride salts and compounds with a wide range of fluoride concentrations in the form of solutions or gels, indicated that repeated applications, semi-annual, or more frequently, give an average caries inhibition in the region of 40 % (Stookey, 1990).

The cariostatic action of fluoride in combination with the physical properties of the teeth is very complex and is considered to be the result of a combination of several factors. When fluoride is applied in high concentrations to enamel, hydroxyapatite is converted to fluorapatite, this being less soluble in an acid environment (Volker, 1939; Margolis and Moreno, 1990). However, according to Fejerskov et al. (1981), no clear relationship has been demonstrated between the fluoride concentration found in the "solid" state of the enamel lattice and caries experience of an individual. It has however, been suggested by Arends et al. (1983, 1990), that the loosely bound fluoride adsorbed onto the surface of the enamel crystals and fluoride in the "liquid" phase around the crystallites, is more likely to be responsible for the caries preventive effect of fluoride. Featherstone et al. (1990) proposed that improved resistance to caries might not necessarily be derived by simply increasing the fluoride concentration. They suggested that application of fluoride in relatively low concentrations, over a longer time period, might be more effective in inhibiting apatite demineralization and in enhancing remineralisation.

In general, both in-vitro and in-vivo, fluoride varnishes show superior fluoride uptake at the tooth surface, but also at greater depths into subsurface enamel, compared with other topical fluoride agents such as aqueous solutions and gels (Petersson, 1976). This finding is common to both primary and permanent teeth. However, both the uptake and retention of fluoride is more pronounced with *Fluor Protector* even though it contains much less fluoride than *Duraphat* (Edenholm et al., 1977; Arends et al., 1980). This can be explained since *Fluor Protector* is acidic and forms hydrogen fluoride, which promotes a much faster fluoride ion diffusion compared to fluoride ions at neutral pH (Arends and Christoffersen, 1990). The much lower viscosity and the ease of flow of *Fluor Protector* are also factors suggested to favour diffusion of fluoride ions in microporosities in the "liquid" state along the hydroxyapatite crystallites. The varnish thereby acts as a local "inhibitor" during dissolution of the enamel in the caries process (de Bruyn, 1987).

In vivo, the F uptake is reported to be increased if *Fluor Protector* is reapplied one week after the initial application (Bruun et al., 1980). Retief et al. (1985) also showed that the total fluoride uptake by enamel increased as contact time increased from two to four hours.

After topical fluoride application, especially when using a high fluoride concentration, a deposition at the enamel surface of mainly calcium fluoride (CaF_2) occurs, which dissolves rather quickly (Brudevold et al., 1967). Arends and co-workers (1980) found the fluoride concentration after treatment with *Duraphat* and *Fluor Protector* exceeded the theoretical level for fluorapatite (~3.8% F) and was similar to a calcium fluoride-like material. Nelson et al. (1984) and Ögaard (1990) have suggested that large amounts of "CaF₂-like" material were retained in enamel after fluoride varnish treatment. Rølla and Saxegaard (1990), confirmed that the CaF₂ layer on the enamel is coated by phosphates and proteins from the saliva and might be acting as a pH controlling reservoir of fluoride that serves to control demineralization and promote the remineralization process (ten Cate, 1990).

There is no doubt that fluoride varnish has a significant caries reducing potential. A number of clinical studies during the last decades have suggested caries reductions following topical fluoride varnish applications, in the permanent dentition, ranging from 20-70% compared to untreated controls (Seppä, 1982; de Bruyn and Arends, 1987). It is however, important to consider that the clinical results are strongly influenced by a number of factors such as caries prevalence and incidence in the study population, the frequency of application of the varnish and the actual levels of caries risk of the children. Much of this research was performed and reported several years ago, and to be relevant for the process of choosing a caries preventive measure, such research needs to be repeated periodically to take into account the effects of changes in caries patterns that are occurring.

Although there are two major fluoride varnish brands on the market, the majority of clinical studies have been carried out with *Duraphat*. In spite of considerable differences in fluoride concentrations and chemical composition, there is little evidence in the literature indicating any significant clinical differences in cariostatic effect between the two varnishes (Petersson, 1993).

Generally the choice of a varnish should be made on the basis of cost effectiveness and safety - i.e. achieving the maximum caries inhibition for the lowest cost (Cohen and Henderson, 1988) - and using the lowest amount of fluoride. Furthermore, almost all the controlled clinical trials investigating the effect of fluoride varnish have been performed in industrialized countries and the applications carried out in well equipped clinics by dentists and dental auxiliaries. Few studies have investigated the caries preventive effects of a fluoride varnish programme in a developing country and where applications have been made by lay persons. A summary of the results of selected clinical trials is presented in Table II.

Fluoride varnish for community-based caries prevention in children

Table II.
Clinical trials with Duraphat (D) or Fluor Protector (FP)

| Study, authors, year | Age at base-line | Duration years | Caries prevalence in community | Type/mode | Varnish group, n | Control group, n | Caries reduction |
|----------------------------|------------------|----------------|--------------------------------|-----------------------|------------------|------------------|-------------------|
| Primary dentition | | | | | | | |
| Holm, 1979 | 3 years | 2 | low-medium | D, semi-annual | 225 | 113 | 43% P < 0.05 |
| Frostell et al., 1991 | 4 years | 2 | low-medium | D, semi-annual | 113 | 93 | 37% p < 0.01 |
| Grodzka et al., 1982 | 3 ½ years | 2 | high | D, semi-annual | 95 | 127 | 9% NS |
| Twetman et al., 1996 | 4 years | 2 | low | FP, semi-annual | 442 | 374 | 29% p < 0.05 |
| Permanent dentition | | | | | | | |
| Koch et al., 1979 | 14 years | 2 | low-medium | D, semi-annual | 98 | 99 | 43% p < 0.05 |
| Clark et al., 1987 | 6-7 years | 5 | low | D, semi-annual | 200 | 189 | 25% p < 0.05 |
| Seppä & Pöllänen, 1987 | 10-13 years | 2 | medium | D, semi-annual | 61 | 62 | 38% p < 0.01 |
| Seppä & Pöllänen, 1987 | 10-13 years | 2 | medium | FP, semi-annual | 62 | 62 | 14% p < 0.05 |
| Modéer et al., 1984 | 14 years | 3 | medium | D, quarterly | 87 | 107 | 36% # p < 0.05 |
| Petersson et al., 1991 | 11 years | 3 | medium | D, three times a year | 71 | 75 | 41% # p < 0.05 |

Effects in primary dentition

Relatively few clinical studies have been performed on the effectiveness of fluoride varnishes for preventing caries in primary dentition and the results are somewhat inconclusive. Some investigators have reported a limited reduction of caries in small children with high caries levels (Murray et al., 1977; Grodzka et al., 1982; Peyron et al., 1992) whereas others demonstrated a significant reduction in preschool children with a low and moderate caries experience (Holm, 1979; Frostell et al., 1991). In a recent study in a low caries level community, the effect of semi-annual applications of a fluoride varnish, *Fluor Protector*, was investigated during a two-year-period in children aged 4 to 6 years. The results shown in Table III give a significant reduction of approximal caries incidence in children who had caries at the baseline examination, thus demonstrating a considerable cost-benefit effect with the use of the varnish (Petersson et al., 1996).

Table III.
Approximal caries incidence during two years in relation to total caries prevalence at baseline in preschool children (Petersson, Twetman & Pakhomov, 1996)

| dfs at baseline | Fluoride varnish group | | | Reference group | | | p | % caries reduction |
|-----------------|------------------------|------|------|-----------------|------|------|--------|--------------------|
| | n | mean | ±SD | n | mean | ±SD | | |
| 0 | 1755 | 0.52 | 1.35 | 1428 | 0.53 | 1.36 | ns | - |
| 1-4 | 345 | 1.20 | 1.80 | 330 | 1.48 | 1.95 | p<0.05 | 19 |
| ≥ | 145 | 1.73 | 2.00 | 158 | 2.30 | 1.98 | p<0.05 | 25 |

Effects in permanent dentition

In the permanent dentition most controlled clinical trials of semi-annual or more frequent applications, have shown statistically significant reductions in caries incidence in the range of 20 - 60% (de Bruyn and Arends, 1987). A recent statistical meta-analysis of the results from a series of studies using *Duraphat* indicated an overall caries reduction figure of 38% in permanent teeth (Helfenstein and Steiner, 1994). It should be noted that no clinical benefits have been demonstrated from annual applications of fluoride varnish. In caries-active teenagers, applications of fluoride varnish four times a year were shown to be beneficial in reducing approximal caries progression (Modéer et al., 1984). However, in teenagers with low caries activity, applications four times a year, were no more effective than

semi-annual applications (Seppä and Tolonen, 1990). Holm et al., (1984) reported a significant reduction in fissure caries of the first permanent molars after three treatments a year with fluoride varnish.

It has recently been suggested that an intensive mode of varnish application, whereby three consecutive applications are made within a 10-day period once a year, was more cost-effective than the regular mode of semi-annual applications (Pettersson et al., 1991; Pettersson and Westberg, 1994; Sköld et al., 1994). A direct dose-response relationship does not appear to exist, as no difference in efficacy between a low fluoride varnish and a regular preparation has been demonstrated (Haugefjorden and Nord, 1991; Seppä et al., 1994).

The clinical effect of fluoride varnish treatments has been shown to be very similar to fluoride mouth rinsing programmes (Koch et al., 1979; Seppä and Pöllänen 1987) but with a relatively higher cost. Therefore a fluoride varnish programme may not be considered as a first option in a community where caries levels are low. It could however, be recommended for children and young adults with high caries risk and with moderate or high caries prevalence. Fluoride varnish may also be the method of choice for adolescents attending private practitioners, who are not covered by school oral disease prevention programmes.

2.2 Fluoride metabolism, side-effects and safety

From a toxicological point of view it is important to understand the basic principles of metabolism of fluoride in humans. Pharmacokinetic analysis of plasma fluoride concentrations in blood after topical fluoride applications have revealed that the fluoride levels achieved are dependent upon the dose, the absorption of different tissues, body distribution, calcified tissue uptake i.e. by the skeleton and teeth, and dominant renal excretion. All these physiological events occur simultaneously and the different pharmacokinetic rates influence and determine the plasma fluoride concentration (Ekstrand and Whitford 1988; Whitford and Ekstrand, 1988). Cousins and Mazze (1973) suggested that a plasma level of 850 ng/ml is nephrotoxic. The fluoride dose given by *Duraphat* application (with a dose of 2.5 - 11 mg F⁻) results in plasma peaks of about 60 - 180 ng/ml within one hour. This comparatively low fluoride concentration in plasma is explained by the very low bioavailability of fluoride in varnish. This level contrasts with fluoride gels containing 1.23% F⁻, that have a bioavailability of almost 100%, and for which plasma peaks close to 1500 ng/ml have been measured. Thus, the use of fluoride varnishes are preferable from the safety point of view.

Plasma peaks after the use of *Fluor Protector* are extremely low and practically of the same order as found after the use of fluoride toothpastes or fluoride rinses. Thus fluoride varnish treatment is extremely safe and can be recommended even for very small children.

2.3 Recommendations for communities and individuals

Any community caries prevention strategy needs to be based on recent epidemiological data including the prevalence and distribution of caries and where possible the incidence of the disease in the target population. Generally, in a population with high caries prevalence it is more cost effective to institute collective measures that cover all children. While in a low caries population, an approach that targets the high risk group is preferable. The following recommendations are provided for these two situations.

High caries communities

- Fluoride varnish applications for all children, on all teeth, two to four times a year will result in significant caries reductions of 30 to 40%.

Low caries communities

- Fluoride varnish applications should be performed selectively. Children who have already experienced caries, or who have active caries lesions should be treated. Either the intensive regimen (three times within two weeks) or two-four applications a year can be chosen. The decision about the regimen to be used can be based on the age of the children and the organization of the oral care delivery service. Using these regimes, caries reductions in primary teeth of at least 25% and in approximal areas of permanent teeth, of 20-40% can be expected.

Individuals

Prevention strategies for patients need to be based on careful consideration of their oral disease risk status. A patient's caries risk profile should be established during the initial visits and then updated regularly, whenever there are significant changes in the patient's oral health status. An oral disease risk profile can be made using several techniques:

- Information on the patient's history (medical, social), life-style (factors related to diet, oral hygiene habits), fluoride exposure, other habits (e.g. tobacco use), exposure to oral disease promoting substances or risks related to occupation etc.
- A clinical evaluation.
- Laboratory tests that count caries-related bacteria in saliva and plaque and saliva secretion rate and buffer capacity.

Such tests can be used to select patients with high risk for dental caries for an intensified prevention regime, that could be offered to patients at high risk, and may well include the application of a fluoride varnish. It is the practitioner's responsibility to devise a regime suited to a patient that is both effective and affordable. Caries progression rates of the patient determined from clinical examination and radiographs over time, also provide essential information for decision-making regarding use of different preventive regimes.

Figure 1. The teeth are cleaned with a pumice paste in order to eliminate dental plaque and facilitate adhesion of the varnish.



Figure 2. After polishing the teeth are rinsed with water spray and dried with a gentle stream of air.



Figure 3. All teeth and accessible surfaces should be treated one quadrant at a time. The varnish should be applied in a thin layer. Special care should be taken to avoid excessive contact of the varnish with the gingival tissues and oral mucosa.



Figure 4. The proximal surfaces are treated from the buccal as well as the lingual direction. The varnish is allowed to set for a few minutes.



3. Guidelines for demonstration projects using fluoride varnish.

These guidelines have been prepared as a result of experience gained using fluoride varnish in a study of more than 5,000 pre-school children by 200 oral care professionals in the County of Halland, Sweden during 1990 - 1994.

3.1 Project planning and preparation of protocol

A detailed protocol is needed, that includes the following items:

- a statement of the problems to be investigated;
- a short literature review;
- the aims of the study and the hypothesis to be tested;
- a description of the methodology, including details of the selection of subjects and constitution of the different study groups;
- method of registration and examination;
- statistical methods and proposed tests for evaluation of the results;
- a time schedule;
- a budget.

3.2 Selection of study groups

It is generally appropriate to run a demonstration project on caries prevention as a longitudinal study with one or more treatment groups that are compared with a reference or control group that does not receive treatment. The size of the sample in each group depends on :

- the prevalence and incidence of dental caries in the community;
- the age of the subjects;
- the organization of the educational and dental care systems;
- the comparisons being made in the study.

Generally, the lower the caries prevalence in the population, the larger the number of subjects required for an investigation.

Ideally the sample for a demonstration project should be derived from the whole population so that the results can then be used to plan programmes for that population. An alternative approach is the random assignment of subjects from a list of all individuals born within a specified time period.

A prerequisite during the planning stage is to have access to recent accurate data on caries in the age groups being considered for inclusion in the investigation.

Fluoride varnish for community-based caries prevention in children

An important decision is the age range of subjects to be included in the project. From the dental point of view, two age ranges are suitable for this type of study.

The pre-school age group (3-5 years) offers a primary dentition unaffected by exfoliation, a potential caries increment as there are a number of tooth surfaces at risk. Although very young, this age group is usually compliant and accepts non-invasive preventive treatments such as varnish application.

The second age group of interest is teenagers aged 12 to 16 years. In this age range a large number of newly erupted permanent teeth are subject to cariogenic challenge. In many countries, children of this age still attend school, and so the treatment can be easily organized within the school system.

It is also important that the sample remain intact and thus accessible for the follow-up examinations for the full period of the study (i.e. two-three years). For this reason, information on local migration or relocation patterns is needed and the sample size at baseline increased if there is likely to be substantial migration away from the study site(s).

Treatment and reference or control groups must be balanced with respect to age, sex, socio-economic levels and caries prevalence. There are two ways to achieve this - through a random assignment of subjects to the study groups, or by assigning matched subjects to each group.

3.3 Training and calibration of examiners

Since many clinicians may be involved in a community project, efforts must be made to ensure the reliability of the clinical examinations. The entire study team should be informed about the purpose of the study and the technical and administrative tasks involved. All examiners must be trained and calibrated, irrespective of their clinical experience. Training and calibration sessions should incorporate examination of subjects who include the complete range of severity of caries likely to be found in the study.

It is convenient to use the caries criteria provided in the WHO manual *Oral Health Surveys: Basic Methods*, 4th edition (WHO 1997). The findings can be recorded on the standard Oral Health Assessment Form. However, where more detailed data is to be collected, other types of recording sheets will need to be used.

Immediately prior to the start of the study, a limited number of children should be examined and then re-examined after one-two weeks, by the same examiners. This exercise will enable the study team to practice working together and will validate the calibration.

3.4 Approvals

Prior to the implementation of the project, application forms should be forwarded to the relevant authorities for approval e.g. the National Health Authority, the local ethical committee or the National Drug Agency. The possible need for special patient insurance for those participating in the study needs to be investigated.

3.5 Patient consent

Consent from patients and their parents should be obtained after they have been provided with verbal and written explanations about the study. In some situations, e.g. when a treatment is part of an established community health programme, collective consent may be arranged by the responsible health authorities.

3.6 Baseline examinations

A manual giving the criteria and scoring procedures, translated into the local language, should be available to all the team members. Clinical examinations should be standardized - a good dental light, compressed air or other means to obtain dry conditions - facilitate the maintenance of a standard examination procedure.

It is important to perform the examination in a systematic sequence - checking quadrant by quadrant, and all tooth surfaces in a fixed order. DFT (dft) or DFS (dfs) indices are most commonly used for such studies; it is recommended that data on lost or missing teeth are also recorded.

If bite-wing radiographs are used for the investigation, film holders must be used in order to assure reproducible projections for assessments of this information. It is essential to use the correct exposure times and dark room procedures so that under or over exposed radiographs are avoided, on which caries diagnosis is seriously jeopardized.

Examination forms should be checked at the end of each day for accuracy and sent for computer data entry as soon as possible after collection. It is an advantage to analyze and evaluate the results from the baseline examinations immediately these have been completed. Bias or inconsistencies may be able to be corrected at this early stage, by adjusting the subjects in the treatment and control groups or by repeating examinations.

The baseline data can also be shared with the personnel from participating clinics. Providing information periodically about how the study is proceeding to those involved helps maintain their motivation. Treatment must be carried out in a standardized manner according to the study protocol, see Annex 1.

3.7 Follow-up and final examinations

The follow-up examinations must be performed at designated time intervals using the same criteria and standardized examination technique as for the baseline examination. A strategy to deal with data on children who are not available for all examinations must be established in the analysis plan in the protocol. A record must be kept of all such drop-outs and efforts made to find out and record the reasons for such absences.

It is of crucial importance that information on any side effects following treatment be recorded. This should include allergic and other serious reactions and any complaints about the taste of the varnish or reasons for poor compliance of the subjects.

3.8 Statistical Methods

As part of establishing the protocol for the study, advice from a statistician should be sought to ensure appropriate sample sizes, and to establish a plan for the analysis of the data to be collected. Basic tables of prevalence, and distribution of the variables should be prepared and the data and results tested for normality. In community-based studies an analysis of variance (ANOVA) is often the test of choice. While in studies with a smaller sample size, nonparametric methods are preferred.

3.9 Evaluation of results

When all the data is available, the analysis of the results for the whole study can be made. Then detailed analysis for subgroups of the sample, can be made in order to elucidate effects of factors such as risk assessment, past caries experiences at baseline etc. The preliminary results should be provided to participating clinic personnel. Data for each clinic should also be provided.

Appraisals of the costs of the project can provide information to assist in making recommendations for future preventive programmes. Cost effectiveness and cost benefit calculations can be made.

3.10 Reporting

The investigators should make the results of the study, whatever the outcome, available to the public, colleagues and decision makers within the community. Conclusions should be provided to members of the community through a report in the local language newspaper. A report should be prepared and submitted to a refereed scientific journal.

Annex 1 - Fluoride varnish application technique

This section provides a step-by step description of the application procedure for fluoride varnish. The scientific rationale for each step is also given.

The total time for the complete treatment is dependent on the age and cooperation of the patient and the equipment available, but is of the order of 10 to 15 minutes per child.

1. Cleaning

All teeth must be cleaned before the application of the varnish is made. The rationale is to secure adhesion and thus prolong the retention of the varnish. Clean all the teeth in each quadrant using a slowly rotating rubber cup and pumice paste or an oil-free medium grade abrasive polishing paste, see Figure 1. Clean all accessible tooth surfaces. Approximal areas can be cleaned with the aid of unwaxed dental floss. Special care to avoid provoking gingival bleeding is needed.

The teeth can also be cleaned by toothbrushing by the patient, depending on the age of the children. This approach limits the time spent for prophylaxis (de Bruyn and Arends, 1987) and thus would improve the cost effectiveness of the treatment. Whichever alternative is chosen, a general rule is "**Varnish application after plaque elimination**".

2. Isolation and drying

The teeth in each quadrant should be isolated with cotton rolls. The teeth must then be dried with compressed air (Figure 2). A saliva aspirator system is useful to maintain the dry conditions essential for correct application of the varnish. A dry surface enhances varnish adhesion, setting hardening and fluoride uptake in enamel.

3. Application

There are several ways to apply varnish; the most important point is to apply it in a thin layer and avoid spreading it onto the soft tissues (Figures 3 and 4).

Several devices have been proposed by clinicians and manufacturers including:

- small brush
- carpule-syringe with blunt needle
- disposable plastic pipettes
- mini-ball burnisher (suitable in fissures)
- In narrow approximal spaces, unwaxed dental floss can be used as a carrier for fluoride varnish.

Fluoride varnish for community-based caries prevention in children

There is however, no scientific evidence to suggest that any of the different methods of application is more effective than another.

4. Setting

In the humid environment present in the oral cavity, the varnish sets in a few minutes. To speed up setting, dry the varnish with a gentle stream of compressed air.

5. Instructions for the patient

When all quadrants have been treated the patient and the parents should be advised that eating and drinking should be avoided for at least two-four hours after the varnish application. Furthermore, no oral hygiene procedures including the use of floss should be carried out the same day since this would remove the fluoride varnish.

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Fluoride varnish for community-based caries prevention in children

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