

## Guidelines on the use of fluoride in children: an EAPD policy document.

### SUMMARY

The EAPD strongly endorses that the daily use of fluoride should be a major part of any comprehensive preventive program for the control of dental caries in children. Regardless of the type of program, community or individually based, the suggested use of fluoride must be balanced between the estimation of caries risks and the possible risks for toxic effects of the fluorides. Such a preventive program should be re-evaluated at regular intervals and adapted to a patient's needs and risks. For the majority of European communities, the EAPD recommends the use of appropriate fluoride toothpaste in conjunction with good oral hygiene to be the basic fluoride regimen.

*Key words: Fluoride, Caries, Child*

### 1. Background considerations

The European Academy of Paediatric Dentistry (EAPD), in collaboration with the Hellenic Division of EAPD, organised a workshop in Athens, Greece (June, 1997), aiming at drawing up guidelines for future use of fluorides among European children. The first draft of these guidelines was published in the EAPD newsletter, and members were invited to make comments and suggestions. The revised first draft was then presented at the biannual EAPD Congress in Sardinia (1998), where it was discussed in great detail, so that members' viewpoints were taken into consideration. The major concepts of the proposed guidelines were approved, and a working group, consisting of the authors of the original paper, was authorised to finalise and publish the recommendations [Oulis et al., 2000]. In November 2008 the EAPD organised another workshop, again in Athens, Greece, to update the original fluoride guidelines. These updated fluoride guidelines employed the evidence-based SIGN (Scottish Intercollegiate Guidelines Network) methodology for ranking the levels of evidence and the grades of recommendations [SIGN 83, 2005; SIGN 50, 2008].

### 2. Introduction

Evidence suggests that the cariostatic effect of fluoride is mostly exerted by its topical rather than systemic effect [Featherstone, 1999]. This effect might be even greater when combined with good oral hygiene, such as when practised as compre-

hensive tooth brushing with a fluoride toothpaste [Rolla et al., 1991]. Concern about the prevalence of dental fluorosis in some children has mostly been related to the use of fluoride supplements, especially during the first 6 years of life [Ismail and Bandekar, 1999]. However, it has also been shown that early exposure to fluoride toothpaste might be a risk factor [Levy et al., 1995; Mascarenhas and Burt, 1998]. Studies that have summarised the risks for dental fluorosis have concluded that the risk is highest when the exposure takes place in both the secretory and the maturation phases of enamel formation [DenBesten, 1999; Evans and Stamm, 1991]. Therefore, three age groups can be considered in terms of having a risk for enamel mottling, namely:

#### 0-4 years

Babies and infants under the age of 4 years of age are considered to be at risk of dental fluorosis of permanent incisors and first molars because the calcification and maturation of these teeth occurs during this period of life. More specifically, the period spanning from 15 to 30 months of age is called the "susceptibility window" as this has been estimated as the highest risk period [Evans and Stamm, 1991]. It is during this period when the use of fluorides must be carefully monitored and balanced with the need to prevent the occurrence of early childhood caries. Special attention should be given to the use of topically applied fluorides during this period of life, because of the inadequate control of the swallowing reflex.

#### 4-6 years

The posterior teeth (premolars and second molars) are calcifying and maturing during this period and at risk of dental fluorosis. Nevertheless, when this occurs it represents less of an aesthetic problem, which needs to be weighed against the marked benefit of caries prevention brought about by the use of fluoride.

#### 6 years and above

The risk for enamel mottling during this period is negligible, with the exception of third molars.

### 3. Guidelines

The following guidelines are recommended as an integral part of preventive programs for children. It must be emphasised, however, that any dentist supervising a child's oral care must address individual needs.

### **I. Water Fluoridation**

Water fluoridation is the controlled adjustment of the natural fluoride concentration in drinking water to that recommended for optimal dental health. Water fluoridation is effective at reducing caries [McDonagh et al., 2000; Griffin et al., 2007, National Health and Medical Research Council, 2007] and has been hailed as one of the 10 greatest achievements in public health in the 20th century [Centers for Disease Control and Prevention, 1999a,b]. It is socially equitable, in that it is available to all social groups and ages. With the exception of dental fluorosis, no association between adverse effects and water fluoridation has been established [McDonagh et al., 2000; National Health and Medical Research Council, 2007]. The development of dental fluorosis is influenced by the total fluoride ingestion from all sources, including toothpaste, during tooth development.

In recent years, the use of bottled drinking waters has become more extensive. These bottled waters, when containing optimal fluoride levels, may play a role in caries prevention. However, further research on the role of fluoride-containing bottled waters, dental caries and fluorosis is needed.

The EAPD reaffirms its support for the use of water fluoridation as a community-based intervention to prevent dental caries.

### **II. Fluoride Tablets & Drops, Fluoridated Milk and Fluoridated Salt**

Fluoride tablets and fluoride drops (traditionally termed fluoride supplements), fluoridated milk and fluoridated salt have been available for decades. Initially their use intended to mimic the consumption of fluoride from naturally fluoridated water in areas without fluoride in drinking water. Now the common view is that it is through the topical effect on tooth surfaces that fluorides have a caries preventive action [Hellwig and Lennon, 2004] and the term "supplements" should be avoided. Use of fluoride-containing toothpastes is almost universal, but other fluoride sources may have an additional effect when the caries challenge is considerable according to an individual's caries-risk assessment. As the systemic effect of fluoride plays a more minor role in caries inhibition it may be argued that fluorides should be applied locally and not given systemically. However, the efficacy and safety of water fluoridation [Yeung, 2008] indicate that systemic distribution of fluoride might be acceptable when this form seems to be the most convenient approach. One Cochrane review

which aimed to examine the effect of additional topical fluoride compared with toothpaste alone, found a modest reduction in caries compared with toothpaste only [Marinho et al., 2004]. Some individuals experience an increased caries challenge and are often termed to be "patients at risk". In general, newly erupted teeth are more prone to caries [Arrow, 2007] and thus specific ages also might be considered being a "risk" age. Among preschool children many do develop caries before the age of 3 years, especially in underprivileged groups, and there might be reason to consider an early start of a preventive program [Wendt et al., 2001; Scottish Intercollegiate Guidelines Network, 2005; Skeie et al., 2005]. On the other hand, dental fluorosis is more likely to occur the earlier the supplement is introduced [Wang et al., 1997]. Studies indicate that mild to moderate dental fluorosis is a significant side effect of fluoride supplements [Ismail and Hasson, 2008]. Another problem with alternative fluoride sources to toothpaste, is the compliance within targeted groups [Horowitz, 2000].

The use of fluoridated toothpaste is the basic caries prevention recommended for all and this should be promoted towards all individuals and caregivers. In cases when tooth brushing is not carried out according to recommendations [Alm, 2008] or the caries-risk is increased for other reasons, then additional sources of fluoride could be useful. However, according to recent evidence-based reports on fluoridated milk, fluoridated salt, fluoride tablets and fluoride drops there is lack of evidence to make good recommendations [Swedish Council on Technology Assessment in Health Care, 2002; Yeung et al., 2005; National Health and Medical Research Council, 2007;] and many of the studies "are highly biased" [Ismail and Hasson, 2008]. Lack of good studies or evidence does not necessarily mean that these methods do not work. There is a general need for well-designed studies which addresses these matters. But the time when negative controls can be defended is definitely gone, so it is now more complicated to obtain the research answers needed.

#### **Fluoridated milk**

Two evidence-based reviews [Yeung et al., 2005; National Health and Medical Research Council, 2007] indicate that there is limited support that fluoridated milk has a caries-preventive effect. However, there is only one randomised controlled trial (RCT) rated 1+ [Maslak et al., 2004] in a recent review [Espelid, 2008]. The assignment system is according to the level of evidence defined in

SIGN50 [Scottish Intercollegiate Guidelines Network, 2008]. This study by Maslak et al., [2004] had a low attrition of participants during the 3 year study period. The results indicated a caries preventive effect of fluoridated milk. Six-year-old children using fluoridated milk since the age of 3 years, had 76.4 % ( $p < 0.05$ ) lower DMFT (first permanent molars) compared with the control group. For primary teeth a significant caries reduction was also demonstrated (31.3 %,  $p < 0.05$ ). Typically fluoridated milk is used in limited groups of children in kindergartens, but there are insufficient studies of good quality examining the effects of fluoridated milk in preventing dental caries [Yeung et al., 2005]. The fluoride concentration in milk is usually in the range 2.5-5.0 mg F/L.

### **Fluoridated salt**

Fluoridated salt is widely used in Germany, France and Switzerland with 30-80% of the marketed salt for domestic use being fluoridated [Marthaler and Petersen, 2005]. More than 30 other countries worldwide use fluoridated salt and this type of fluoride delivery is highly recommended by WHO. Salt is most commonly fluoridated at 250 mg of fluoride per kg [Gillespie et al., 2005]. There is no RCT conducted on this topic according to recent reviews [Swedish Council on Technology Assessment in Health Care, 2002; National Health and Medical Research Council, 2007; Espelid, 2008;]. Some cross-sectional studies and controlled clinical trials do indicate a caries preventive effect of salt, but fluoridated salt is probably less effective among small children due to the low salt diet now recommended for this age group.

### **Fluoride tablets/lozenges and fluoride drops**

One well-designed, double blinded RCT indicates that supervised administration of fluoride tablets may be an effective preventive measure among children with high caries-risk [Stephen and Campbell, 1978]. This paper was graded 1+ and had a small drop-out rate [Espelid, 2008]. Another well-designed study graded 1+ could not demonstrate an additional effect of fluoride tablets compared with a positive control (fluoride rinse) [Poulsen et al., 1981]. Some additional RCTs report contradictory findings [Swedish Council on Technology Assessment in Health Care, 2002; Espelid, 2008]. These studies might be more or less biased because they are rated as low quality studies.

**Table. 1** Recommended dosage schedule (assumption is  $< 0.3$  mg F/L in drinking water)

Age	Recommendation
0 – 24 month	none
2-6 years	0.25 mg F/day
7-18 years	0.50 mg F/day

Good practice point for fluoride tablets/lozenges:

If the level of fluoride in drinking water is between 0.3-0.6 mg F/L there should not be any additional fluoride use other than F-toothpaste in the 2-3 years of age group. In the older groups the daily tablet dose should then be reduced to 0.25 mg F/day.

Fluoride for local use has been delivered in drops and in combinations with vitamins. Some caries preventive effect has been reported [Espelid, 2008]. A comparison of fluoride tablets and fluoride drops with a negative control in a RCT showed a significant effect of both methods, after 2 years in a preschool population [Lin and Tsai, 2000]. The best caries preventive effect according to this study was obtained using fluoride drops twice a day compared with the daily sucking of a fluoride tablet (0.25 mg NaF).

### **Recommendation**

Fluoridated milk and fluoridated salt could be a public health measure in target groups with high caries prevalence and low compliance for tooth brushing in areas without water fluoridation. Fluoride tablets and fluoride drops could be considered on an individual basis for children at high risk of caries (Grade of recommendation: C).

### **III. Fluoride Gels, Rinses and Varnishes**

General comment: Topical fluorides should be used in children assessed as being at increased risk for caries development, including children with special oral health care needs. The evidence, recommendations and good practice points for fluoride gels, rinses and varnishes are shown in Table 2.

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**Table 2.** The evidence, recommendations and good practice points for fluoride gels, rinses and varnishes

Modality	Evidence	Recommendation	Good Practice Points		
	Evidence of efficacy	Level according to [SIGN 50, 2008]	Recommendation	Grade according to [SIGN 50, 2008]	
Gels (professional use; 5,000-12,500 ppm F)	<b>Primary teeth:</b> Two trials included in a Cochrane review [Marinho et al., 2002a], but effect in primary teeth uncertain [Poulsen, 2009]	1++	Do not use in children < 6 yrs of age, as risk:benefit ratio is in favour of risk due to danger of swallowing the gel	D	Use 2-4 times per year Obvious deposits of dental plaque should be removed prior to application. In order not to exceed PTD clinicians should [Whitford, 1992]: Use appropriate size trays, and suction devices during and after treatment. Patient should sit in upright position and not swallow Allow child to expectorate Teeth should be wiped at the end of the session with gauze Instruct child not to eat or drink for 20-30 min after application
	<b>Permanent teeth:</b> Efficacious in preventing caries [Marinho et al., 2002a; Poulsen, 2009]	1++	Use for caries prevention in permanent teeth	A	
Rinses (home use or at schools; daily: 0.05% NaF (225ppm F); weekly: 0.2% NaF (900 ppm F)	<b>Primary teeth:</b> No data available [Poulsen, 2009; Marinho et al., 2003b]	-	Do not use in children < 6 yrs of age, as risk: benefit ratio is in favour of risk due to danger of swallowing the rinse	D	Supervised use more efficacious than unsupervised 10 ml of the solution is swished around the mouth for 1 minute Instruct child not to eat or drink 20-30 mins after application
	<b>Permanent teeth:</b> Efficacious in preventing caries [Poulsen, 2009; Marinho et al., 2003b]	1++	Use for prevention of caries in permanent teeth	A	
•Varnishes (professional use; 1,000 – 56,300 ppm F)	Efficacious in preventing caries in both primary and permanent teeth [Poulsen, 2009; Marinho et al., 2002b]	1++	Should be used for prevention of caries in both primary and permanent teeth	A	Use 2-4 times per year Obvious deposits of dental plaque should be removed prior to application In order not to exceed PTD clinicians should take the same precautions as for gels (see above) A thin film using minimal amount should be used Amount could be kept at a minimum by limiting application to surfaces at risk Instruct child not to eat or drink for 20-30 mins after application

#### IV. Fluoride Toothpastes

Clinical effectiveness – The extensive use of fluoridated toothpastes has probably been one of the major reasons for the dramatic reduction in dental caries recorded over the past 30 years. Tooth brushing with fluoridated toothpaste is close to an ideal public health method in that its use is convenient, inexpensive, culturally approved and widespread [Burt, 1998]. The use of fluoride toothpaste in children and adolescents has been subjected to several systematic reviews during the recent decade [Marinho et al., 2003a; Twetman et al., 2003; Ammari et al., 2003, Marinho, 2008] and the caries-preventive effectiveness, expressed as prevented fraction, is summarized in Table 3.

**Table 3.** Factors influencing the caries-preventive effect of fluoride toothpaste as displayed in systematic reviews. Prevented fraction (PF %) with confidence intervals.

Intervention	vs. control	(95% CI)
Fluoride toothpaste	placebo	24 (21-28)
Supervised brushing	non-supervised brushing	11 (4-18)
Brushing twice per day	once per day	14 (6-22)
1,450-1,500 ppm F	1,000-1,100 ppm F	8 (1-16)
F-toothpaste + other fluoride sources*	F- toothpaste	10 (2-17)

\* water fluoridation, fluoride varnish, fluoride gel, or fluoride rinsing

*Potential harm* – One problem with young children's use of toothpaste is that they often swallow considerable amounts with a subsequent risk for dental fluorosis [Mascarenhas and Burt, 1998]. Fluoride toothpaste may be responsible for up to 80% of the daily fluoride intake [de Almeida et al., 2007] and the first 3 years of life seem to be the most critical. Therefore, parents should be strongly advised to use only a pea-size of toothpaste for very young children and assist or supervise tooth brushing until at least 7 years of age. A children's toothpaste with a lower concentration of fluoride may be indicated although the evidence for a caries-preventive effect of formulas with less than 500 ppm F are insufficient [Twetman et al., 2003; Steiner et al., 2004].

Evidence based statements – Based on the conclusions of narratives [Davies et al., 2003; Twetman, 2009] and systematic reviews [Marinho et al., 2003a; Twetman et al., 2003; Ammari et al., 2003], the following evidence-based statements can be formulated as shown in Table 4:

**Table 4.** Statements with level of evidence according to the Scottish Intercollegiate Guidelines Network [2008]

Statement SIGN	Level of Evidence
Brushing with fluoride toothpaste daily prevents caries,	1++
Increasing the frequency of brushing with fluoride toothpaste improves caries prevention,	1+
Adult assistance/supervision of tooth brushing in children improves caries prevention,	2+
Toothpastes containing higher concentrations of fluoride are more effective than those with lower levels of fluoride in preventing caries,	1++
Commencement of tooth brushing prior to 1 year of age reduces the probability of developing caries,	3
Ingestion of fluoridated toothpaste by young children is associated with an increased risk of dental fluorosis.	2-

*Tooth brushing behaviour* – The duration of tooth brushing should exceed one minute on each occasion and children should be encouraged to spit out excess toothpaste and avoid rinsing with water. There is no firm evidence to suggest the ideal timing of tooth brushing but a common recommendation is that children's teeth should be brushed last thing at night before bedtime and on at least one other occasion. Eating directly after brushing should be avoided. Children's teeth can be brushed with either manual or powered toothbrushes with a soft small head.

#### Clinical recommendations

The EAPD recommendations for the use of fluoride toothpaste in children are summarized in Table 5. The daily use of fluoride toothpaste, in combination with oral hygiene instructions, is recommended as the basic part of a caries-preventive program in addition to other caries-preventive methods, such as diet counselling, topical use of fluorides and fissure sealants, which are also

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important. There is good evidence for outreach programs (school or home-based) targeted at vulnerable high caries-risk groups as well as ethnic minorities [Twetman, 2009]. Where fluoride toothpaste is used in conjunction with other fluoride vehicles, the cumulative effect of fluoride must be taken into account for children less than 6 years of age. Care must be taken to ensure that a balance is maintained between maximising the protective effect against dental caries and minimising the risk of dental fluorosis. Furthermore, "best available evidence" must be balanced with the practitioner's expertise and the family's preferences. The background fluoride exposure as well as the socio-economic level of the community may also influence the above-mentioned recommendations.

**Table 5.** Recommended use of fluoride toothpaste in children

Age group	Fluoride concentration	Daily use	Amount to be used daily
6 months-<2 years	500 ppm	twice	pea-size
2-<6 years	1000 (+) ppm	twice	pea-size
6 years and over	1450 ppm	twice	1-2 cm

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