Fluoride GUIDE

Written by Fiona M. Collins, BDS, MBA, MA and Michael Florman, DDS

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Foreword

Optimizing a fluoride protocol for individuals at dental caries risk is the most important measure that can be done to prevent future and arrest current disease. However, fluoride therapy remains complex and controversial. Since the introduction of water fluoridation, fluoride supplements, and topical fluoride therapies in the late 1940s, the mechanisms of action, dosages and delivery systems have been debated and have evolved.

Originally, the mechanisms of fluoride action were ascribed solely to reducing enamel solubility. Now, other mechanisms such as fluoride’s effect on remineralization and its effect on bacterial metabolism also are recognized. Similarly, the initial dosage of fluoride supplements was empirical, based on simulating fluoride exposure from optimally fluoridated water. As a result of epidemiologic studies showing mild fluorosis in some children with the original dosage and the fact that fluoride is now a ubiquitous part of a child’s diet, the fluoride supplement dosage has been altered several times over the past 30 years. These issues of dosage are further compounded by epidemiologic studies showing changing prevalence of caries and fluorosis.

Topical fluoride use in preschool children, as well, has evolved. New modalities, such as fluoride varnishes, have become more prevalent for office treatment for children because of the safety of premeasured doses, ease of application and better patient acceptance.

Overlaying both the issues of topical fluoride therapy and fluoride supplement use is the current focus on individualized therapy for patients based on caries risk. One should no longer prescribe fluoride supplements or perform a professionally applied topical fluoride treatment without considering an individual’s caries risk. Recent recommendations suggest limited use of fluoride for those at low caries risk, but significantly more frequency and intensity for those at high risk.

This Fluoride Guide addresses the current concepts of fluoride mechanism, systemic and topical therapy based on the best evidence in the literature. Not only does the Guide provide scientific rationale, it also offers the dental provider options, based on efficacy for systemic fluoride, office treatments and home-use fluoride products.
Educational Objectives

The overall goal of this article is to provide the reader with information on the use of systemic and topical fluorides for caries prevention.

Upon completion of this course, the dental professional will be able to do the following:
1. List intentional and unintentional sources of systemic fluoride.
2. List and describe caries risk factors and the ADA recommendations for in-office topical fluorides corresponding to different risk levels.
3. List and describe the considerations involved in selecting in-office and home-use topical fluorides.
4. List and describe the various home-use topical fluorides available and the clinical efficacy of each.

Abstract

Water fluoridation heralded the use of fluoride as an anti-caries agent. Since that time, both systemic and topical fluorides have become available and the use of fluorides has contributed greatly to reducing the level of caries seen in the population. Systemic fluoride supplements are available as tablets and drops, for use in accordance with the recommendations on fluoride supplement dosing. Vehicles for topical fluorides include in-office fluoride varnishes, gels, and foams, and home-use fluoride dentifrices, rinses and prescription products. The primary mechanisms of action involved with the use of topical fluorides are the prevention of demineralization and promotion of remineralization, by ensuring the ready availability of intra-oral fluoride.

Considerations in selecting an appropriate in-office and home-use topical fluoride protocol for individual patients include the patient’s age, caries risk level, exposure to fluoride from all sources, and the current recommendations on professionally-applied topical fluorides. Other important considerations include product efficacy and safety, the patient’s dental status as well as compliance with brushing and age-appropriate use of fluoride toothpaste, and clinician and patient preferences.
Introduction

Fluoride has been used in the United States as an anti-caries agent since the 1940s, when water fluoridation was first introduced. Since then, numerous agents have become available for both the systemic and topical applications of fluoride.

Currently available fluorides include sodium fluoride, sodium monofluorophosphate, acidulated phosphate fluoride and stannous fluoride. In addition to its use as a caries preventive to help prevent demineralization and aid remineralization, fluoride is used for the treatment of dentinal hypersensitivity.

The focus of this guide is on the anti-caries benefits of fluoride. Systemic and topical fluorides will be addressed, including the mechanisms of action, categories of fluoride products and evidence for their use, as well as current recommendations on systemic and topical fluorides.

Systemic fluoride

Intentional sources of systemic fluoride for the prevention of caries include fluoridated water and fluoride supplements. Inadvertent (unintentional) sources include naturally occurring fluoride in well water, fluoride toothpaste, brewed tea, bottled water, drinks and goods processed using fluoridated water, and foods such as fish. In addition, certain medications contain fluoride. (Table 1)

Table 1. Sources of systemic fluoride

<table>
<thead>
<tr>
<th>Intentional</th>
<th>Unintentional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoridated water</td>
<td>High fluoride level well water</td>
</tr>
<tr>
<td>Fluoride supplements</td>
<td>Foods containing fluoride</td>
</tr>
<tr>
<td>Fluoridated salt</td>
<td>Home-use topical fluoride products, including fluoride toothpaste</td>
</tr>
<tr>
<td>Fluoridated milk</td>
<td>Medications containing fluoride</td>
</tr>
<tr>
<td>Fluoridated foods</td>
<td>High fluoride level bottled water</td>
</tr>
</tbody>
</table>

Water fluoridation

Water fluoridation was first introduced in the 1940s,1 and its use has resulted in substantial declines in caries rates. Water fluoridation, as a public health measure, is achieved through the addition of fluoride at water plants, typically to obtain a level of 1 ppm fluoride in drinking water. In other areas where the level of fluoride is substantially higher than the recommended level, excess fluoride can be removed during processing.
**Fluoride-enriched salt**

Fluoridated salt has been used in several areas of the world, including parts of Europe and Latin America. A recent review of the literature led to the determination that there are no randomized, controlled clinical trials on the use of fluoridated salt to enable conclusions to be drawn as to its efficacy. The same reviewer located two studies on fluoridated milk, one of which showed, at the conclusion of the study, a significant reduction in caries in children age 8 after three years of use.2

**Fluoride supplements**

Fluoride supplements can be given to at-risk children as drops, lozenges or tablets, with the dose varying with the level of fluoride contained in the domestic water supply and age of the child. The use of fluoride supplements by pregnant women does not result in any benefit for the baby.

- Current recommendations from the American Academy of Pediatric Dentistry, American Dental Association and American Academy of Pediatrics are to start fluoride supplements, if required, at 6 months3,4 (Table 2)
- The Centers for Disease Control and Prevention (CDC) suggests that fluoride supplements be given to children living in areas with suboptimal water fluoridation who are at high risk of caries5
- Chewing or sucking fluoride tablets and lozenges prior to swallowing will maximize the effect of these supplements by providing an additional topical effect.

**Table 2. Recommended fluoride supplement dosing (mg/day)**

<table>
<thead>
<tr>
<th>Age of Child</th>
<th>Fluoride in domestic water supply</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 0.3 ppm</td>
</tr>
<tr>
<td>Up to 6 months</td>
<td>None</td>
</tr>
<tr>
<td>6 months to 3 years</td>
<td>0.25 mg/day</td>
</tr>
<tr>
<td>3-6 years</td>
<td>0.5 mg/day</td>
</tr>
<tr>
<td>6-16 years</td>
<td>1.0 mg/day</td>
</tr>
</tbody>
</table>

**Systemic fluoride and mechanisms of action**

During tooth development, the cumulative ingestion of fluoride prior to pre-eruptive enamel maturation results in fluoride ions replacing hydroxyl ions and the formation of fluorapatite crystals instead of hydroxyapatite crystals.6 (Figure 1) The fluorapatite crystals are smaller and stronger than hydroxyapatite crystals and are more resistant to demineralization associated with the dental caries process. Recent reviews have suggested that the effect of fluoride, including that contained in supplements, foods and drinks, is mainly the result of its topical effect.7,8,9
Ingested fluoride works through a number of mechanisms:

- Systemic fluoride use results in a concentration of fluoride of 1,000 – 2,000 ppm in the outer layer of the enamel.
- The remainder of the enamel contains about 20 – 100 ppm.
- Pre-eruptively, formed enamel is bathed in plasma that contains fluoride and contributes to the outer fluoride-rich layer.
- Post-eruptively, the enamel is bathed in fluoride contained in saliva and crevicular fluid, that was derived from systemically absorbed (ingested) fluoride.
- Both the fluoride-rich layer and the inner layers of the enamel containing 20 – 100 ppm fluoride are still susceptible to acid attacks.\(^{10}\)
- Ongoing caries prevention from fluoridated water and other fluoride-containing drinks and/or foods also occurs as a result of their direct topical effect with some retention of fluoride intra-orally on the teeth and in dental biofilm (plaque).

Inadvertent ingestion of excessive amounts of fluoride during enamel development, from all sources combined, can result in fluorosis and is dependent on the dose, age of the child and duration of excessive fluoride ingestion. A risk of fluorosis with regular use of fluoride supplements and toothpaste has been found, underscoring the importance of total fluoride ingestion when prescribing supplements.\(^{11}\)

**Fluorosis**

Fluoride sources that may contribute to a high total level of fluoride ingested, and therefore fluorosis, include high-fluoride-level well water, foods and drinks containing high levels of fluoride, the repeated ingestion of fluoride intended for topical use only and certain medications.

- Mild fluorosis results in white mottled areas of enamel as a result of hypomineralization, which can be a cosmetic concern in the anterior dentition. Severe fluorosis can result in pitted and malformed areas of enamel, brittle enamel, breakdown of areas of enamel and teeth with abnormal morphology.
- Fluorosis seen in the United States is generally very mild or mild.\(^{12}\)
- Severe fluorosis is more common in areas with high-fluoride-level well water.
- For fluorosis to occur, excess fluoride must be ingested prior to pre-eruptive enamel maturation; ingestion after this developmental phase cannot result in fluorosis.
- Fluorosis as a result of excess ingestion of fluoride from age 6 onward is not a concern as pre-eruptive enamel maturation of the anterior (and majority) of the dentition has been completed by then and for all of the dentition by age 8.
- Topical fluorides are relevant for fluorosis only if inadvertently swallowed.
Topical fluorides

Topical fluorides are available as in-office fluorides and home-use fluorides. Topical fluorides act intra-orally by:

- Providing periodic high doses of fluoride (in-office)
- Providing low regular doses of fluoride (home-use).

Topical fluorides available in the United States include:

- Sodium fluoride
- Sodium monofluorophosphate
- Acidulated phosphate fluoride (or acidulated sodium fluoride)
- Stannous fluoride
- Fluoride from glass ionomer cements
- Other fluoride-releasing dental materials.

Acidulated formulations were first investigated with the goal of increasing fluoride uptake and ion exchange through the use of a low pH. These included phosphate to prevent dissolution of dental hard tissues.\(^{13,14}\) Other investigators focused on formulations that had the potential to bind the fluoride to the tooth surface or to prolong the application for greater fluoride release and availability.

Caries and the mechanism of action of topical fluoride

Dental caries is a multifactorial infectious disease that always requires the presence of cariogenic bacteria – primarily mutans streptococci (\textit{Streptococcus mutans} and \textit{S. sobrinus}) as well as lactobacilli. These bacteria metabolize fermentable carbohydrates, producing acid that is capable of demineralizing dental hard tissues at below pH 5.5, under conditions favoring this. During acid attacks, subsurface dissolution occurs at pH 3.8 – 4.8, with the loss of calcium and phosphate ions from the crystals. The intra-oral pH rebounds approximately 30 minutes after an acid attack, during which time remineralization with calcium phosphate and fluoride ions occurs at the site of demineralization.

As a result of repeated episodes of demineralization (and in the absence of remineralization), white spots may appear due to subsurface demineralization. In orthodontic patients, these white spots can be found adjacent to brackets in particular and are referred to as orthodontic decalcifications.\(^{15}\) Unhindered, once sufficient subsurface structure has been lost, the surface collapses and cavitation occurs. Disease progression is more rapid in dentin as demineralization of the dentin is followed by enzymatic degradation of the exposed collagen fibrils.\(^{16,17}\) (Figure 2, 3)
Figure 2. Caries process: demineralization and remineralization

![Diagram of demineralization and remineralization](image)

Drop in pH as a result of an acid attack results in loss of ions and demineralization of the tooth structure; under favorable conditions, this is followed by the migration of ions to the site of the lesion and remineralization.

Figure 3. Destructive phase of the caries process in dentin

![Diagram of destructive phase in dentin](image)

Drop in pH as a result of an acid attack results in loss of ions and demineralization of the tooth structure; if the lesion is not remineralized, this is followed by degradation of the exposed collagen fibrils resulting in more rapid progression of caries in dentin than in enamel.

Anti-caries benefit of fluoride

The anti-caries benefit derived from topical fluorides can be attributed primarily to the prevention of demineralization and the promotion of remineralization. Ensuring the ready availability of intra-oral fluoride helps prevent demineralization from occurring and, should it occur, aids remineralization. The application of high concentrations of topical fluoride results in the formation of alkali-soluble calcium fluoride-like globules at the tooth surface, the amount being influenced by the length of application and the concentration of fluoride used. These globules act as a fluoride reservoir and have been observed with scanning electron microscopy. It is believed that the phosphate associated with these globules is responsible for their stability at a normal pH. When
Acid attacks occur, the globules start to break down and release calcium, phosphate and fluoride, resulting in a higher concentration of these ions at the tooth surface than internally. These then migrate to demineralized sites and remineralize these defects, also forming fluoridated hydroxyapatite. (Figure 4)

At lower concentrations of topical fluoride (as used in dentifrices and rinses), fluoride is retained in solution in saliva as well as being retained as alkali-soluble calcium fluoride. Thus, topical fluorides result in the retention of fluoride on the tooth surface; in saliva and dental plaque; and on intra-oral soft tissues, especially the tongue and lower posterior vestibule of the mouth.\textsuperscript{18,19,21}

Figure 4. Fluoride adsorption and caries control

High concentrations of topical fluorides result in the formation of calcium fluoride-like globules. These are stable until exposed to acid, when they release calcium, phosphate and fluoride. Low concentrations of topical fluorides also result in the presence of bioavailable fluoride in plaque, saliva and oral mucosa. Together, these mechanisms provide for reservoirs of fluoride available during acid attacks.

Topical fluoride is also believed to inhibit caries activity through bacterial inhibition.\textsuperscript{16} (Figure 5)

Figure 5. Bacterial inhibition

Fluoride combines with hydrogen and then enters the bacterial cell. Following entry into the cell, the fluoride and hydrogen dissociate and the fluoride inhibits enzymes involved in bacterial metabolic processes; this includes inhibition of enolase that metabolizes fermentable carbohydrates, thereby reducing the production of acid involved in the caries process.
Most of the topical effect of fluoride is due to the presence of available fluoride rather than the influence of fluoride uptake during fluoride therapy (in-office or home-use). As previously mentioned, ingested fluoride also contributes to the topical effect of fluorides. Omitting plaque removal with a professional prophylaxis prior to the use of in-office topical fluorides has been found to still result in the formation of calcium fluoride-like globules at the tooth surface and, in fact, to increase fluoride retention and the efficacy of fluoride therapy. Regular rinsing with fluoride in the presence of plaque has been shown to result in the deposition of alkali-soluble (available) fluoride.22,23,24

**Table 3. Fluoride concentration in ppm fluoride**

<table>
<thead>
<tr>
<th>Fluoride Type</th>
<th>Concentration (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5% sodium fluoride varnish</td>
<td>22,600 ppm</td>
</tr>
<tr>
<td>APF gels and foams</td>
<td>12,300 ppm</td>
</tr>
<tr>
<td>Sodium fluoride gels and foams</td>
<td>9,050 ppm</td>
</tr>
<tr>
<td>Dual rinses</td>
<td>3,300 ppm</td>
</tr>
</tbody>
</table>

The selection, use and frequency of use of in-office fluorides for an individual patient should be based on his or her risk level, and should consider ADA recommendations; patient age; product efficacy, clinical support and safety; ease of use and patient preference.

**Varnishes**

In the United States, fluoride varnish is available as 5% sodium fluoride, equivalent to 22,600 ppm fluoride. While the FDA has cleared varnish as a device for the relief of hypersensitivity and as a cavity liner, the vast majority of clinical trials, evidence-based studies and the major use worldwide is as an in-office topical fluoride for the prevention of dental caries. In addition, the American Dental Association recommends the use of 5% sodium fluoride varnish for caries prevention for children of all ages (including children under 6 years of age) and for adults. Both tinted and white/clear versions are available in tubes and/or unit doses. Studies have demonstrated patient preference for white/clear varnish due to the improved esthetics while the varnish remains on the teeth, while clinicians have found the use of unit doses simplifies application, results in the use of a defined amount of varnish and reduces any risk of cross-contamination. Application frequencies of twice or four times per year have been advocated, as well as more frequently than four times per year in some cases of early childhood caries.26,27
Clinical effectiveness

Five percent sodium fluoride varnish has been found to be effective in reducing caries in the primary dentition – including early childhood caries – and the permanent dentition.\textsuperscript{28,29,30,31} Trials and studies have demonstrated reductions in coronal and root caries as well as recurrent caries. One meta-analysis by Marinho et al. pooled data from clinical studies of at least one year’s duration in patients under age 17 who were blinded or double-blinded and met all criteria. They found an overall caries reduction in the primary dentition (dmfs) of 33%, with a range of 19 – 48%, and in the permanent dentition (DMFS) of 46%, with a range of 30 – 63%.\textsuperscript{32} An earlier, smaller meta-analysis with fewer studies had yielded a caries reduction of 38% in children (Helfenstein and Steiner).\textsuperscript{33} In an open study, Weinstein et al. found a significant increase in the reversal of enamel decalcifications in children with early childhood caries.\textsuperscript{34} Studies using 5% sodium fluoride varnish have also reported on its effectiveness in reducing orthodontic decalcification.\textsuperscript{35}

<table>
<thead>
<tr>
<th>Study</th>
<th>Caries reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marinho et al.</td>
<td>Meta-analysis 33% dmfs reduction (19% to 48%)</td>
</tr>
<tr>
<td></td>
<td>46% DMFS reduction (30% to 63%)</td>
</tr>
<tr>
<td>Helfenstein, Steiner</td>
<td>Meta-analysis 38% reduction</td>
</tr>
<tr>
<td>Holm et al. \textsuperscript{36}</td>
<td>Pre-school children 44% dmft reduction</td>
</tr>
<tr>
<td>Weinstein et al.</td>
<td>Early childhood caries (open study) 51% reversal of enamel decalcification</td>
</tr>
</tbody>
</table>

The high level of fluoride and prolonged fluoride release compared to other in-office topical fluorides are factors considered to result in the high caries reductions that have been found with this vehicle.

Gels and foams

Gels and foams are available as acidulated phosphate fluoride and as sodium fluoride. Acidulated phosphate fluoride (APF) gels and foams contain 12,300 ppm fluoride, and neutral sodium fluoride gels contain approximately 9,000 ppm fluoride. These are available as either a four-minute or a one-minute application:

- There is clinical support and evidence for the efficacy of four minute gel applications
- There is insufficient evidence of caries efficacy for a one-minute application of gel or foam
- Foam has the advantage of resulting in a lower dose of applied fluoride compared to gel, reducing the risk of ingestion.
The American Dental Association recommends the use of 4-minute fluoride gel in children age 6 and older and in adults. The use of in-office fluoride gels and foams is not recommended for children under age 6, who are at greater risk of fluoride ingestion during application and have less ability to spit out excess afterward.

**Clinical efficacy**

In a meta-analysis of fluoride gels, a caries reduction average of 21% was found (range of 14 – 28%) across 14 placebo-controlled studies.\(^{37}\) A separate systematic review of 23 trials (some of which did not have placebo controls) found a caries reduction (DMFS) average of 28% (range of 19 – 37%).\(^{38}\) It was also concluded in these studies that there was insufficient evidence of any effect in the primary dentition. A systematic review by van Rijkom et al. of clinical trials using acidulated phosphate gels found an average reduction of 22%, with greater reductions for higher caries incidence patients than for lower caries incidence patients.\(^{39}\) An *in vitro* study by Garcia-Godoy et al. resulted in the conclusion that APF gel treatment with a one-minute or a four-minute application resulted in equivalent reductions in enamel lesion depths.\(^{40}\) A recent study conducted on 3 – 4-year-olds on the twice-annual use of in-office APF foam found a primary caries reduction (dmfs) of 24%, attributable to its effect on approximal surfaces and no effect on occlusal surfaces.\(^{41}\) A second study by Jiang et al. assessed the efficacy of APF foam and gel in 6-7 year-old children in a 24-month clinical trial, and found these were equivalent with a 41% caries reduction on smooth surfaces for each.\(^{42}\) (Table 5) The ADA does not recommend or endorse the use of one-minute gels and does not recommend the use of fluoride foams, due to the paucity of clinical evidence.\(^{25}\)

**Table 5. Clinical efficacy of fluoride gels and foams**

<table>
<thead>
<tr>
<th>Study</th>
<th>Caries reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marinho et al.</td>
<td>Meta-analysis (gel) 21% DMFS reduction (14% to 28%)</td>
</tr>
<tr>
<td>Marinho et al.</td>
<td>Systematic review (gel) 28% DMFS reduction (19% to 37%)</td>
</tr>
<tr>
<td>v Rijkom et al.</td>
<td>Systematic review (gel) 22% average reduction</td>
</tr>
<tr>
<td>Jiang et al.</td>
<td>APF gel and foam comparison 41% caries reduction for each</td>
</tr>
<tr>
<td>Jiang et al.</td>
<td>Pre-school children (foam) 24% dmfs reduction</td>
</tr>
</tbody>
</table>

**In-office fluoride rinses**

In-office topical rinses are available as 2% sodium fluoride rinses and dual rinses containing stannous fluoride and acidulated phosphate fluoride. These should not be used in young children, due to the risk of ingestion.

- There is limited *in vitro* data suggesting an effect for dual rinses
- There is no clinical evidence for efficacy of these rinses
- The American Dental Association does not recommend the use of in-office fluoride rinses.\(^{25}\)
Risk levels and ADA recommendations for in-office fluorides

Patients can be classified as being at low, moderate or high risk for caries at a given time. Low-risk patients are those who have no factors that may increase their risk of caries and who have had no incipient, cavitated or secondary carious lesions in the prior three years, according to the guidelines in the ADA recommendations on professionally applied fluorides. All other patients are either moderate or high risk. (Table 6)

Table 6. Moderate- and high-risk levels

<table>
<thead>
<tr>
<th>Moderate risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>&lt; 6 years of age</strong></td>
<td><strong>6+ years of age</strong></td>
</tr>
<tr>
<td>No incipient/cavitated carious lesions during the last 3 years At least one risk factor</td>
<td>one/two incipient/cavitated lesions in last 3 years and/or at least one risk factor</td>
</tr>
</tbody>
</table>

Adapted from: Evidence-based Clinical Recommendations: Professionally Applied Topical Fluoride

For moderate- and high-risk patients, the American Dental Association recommendations are for the use of fluoride varnish in children under age 6 and either fluoride varnish or a four-minute gel in patients age 6 and over. The recommended frequency of application for these patients is two to four times per year, depending on risk level.\(^{25}\) The ADA recommendations do not include the use of foam specifically because there are few clinical trials conducted on foam to demonstrate its efficacy. However, those that were conducted, together with laboratory data, suggest that it may be equivalent to fluoride gel. For low-risk patients, in-office topical fluorides are not recommended, and the use of fluoride dentifrice may suffice. Professional judgment is required for individual patients.\(^{25}\) (Table 7)

Risk factors are destructive factors in the caries process, while the use of fluoride and other preventives are protective factors. (Table 8)
Table 7. American Dental Association recommendations

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Low-risk patients*</th>
<th>Moderate-risk patients**</th>
<th>High-risk patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 6 years of age</td>
<td>Professional fluoride may be of no benefit</td>
<td>Fluoride varnish 2 times per year</td>
<td>Fluoride varnish 2 - 4 times per year</td>
</tr>
<tr>
<td>6 - 18 years of age</td>
<td>Professional fluoride may be of no benefit</td>
<td>Fluoride varnish or gel 2 times per year</td>
<td>Fluoride varnish or gel 2 - 4 times per year</td>
</tr>
<tr>
<td>18+ years of age</td>
<td>Professional fluoride may be of no benefit</td>
<td>Fluoride varnish or gel 2 times per year</td>
<td>Fluoride varnish or gel 2 - 4 times per year</td>
</tr>
</tbody>
</table>

* Use professional judgment. Fluoride dentifrice may be sufficient. **Moderate-risk may benefit from up to 4 times per year. Adapted from: Evidence-based Clinical Recommendations: Professionally Applied Topical Fluoride.

Table 8. Destructive (risk) and protective factors

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Protective factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suboptimal fluoride exposure</td>
<td>Optimal fluoride exposure</td>
</tr>
<tr>
<td>Poor oral hygiene</td>
<td>High salivary flow</td>
</tr>
<tr>
<td>Familial high caries rate</td>
<td>Use of xylitol</td>
</tr>
<tr>
<td>Enamel defects</td>
<td>Home use of Recaldent-containing products</td>
</tr>
<tr>
<td>Tobacco use</td>
<td></td>
</tr>
<tr>
<td>Exposed roots</td>
<td></td>
</tr>
<tr>
<td>Low SES</td>
<td></td>
</tr>
<tr>
<td>Xerostomia</td>
<td></td>
</tr>
<tr>
<td>High bacterial load</td>
<td></td>
</tr>
<tr>
<td>High frequency sugar and other carbohydrate</td>
<td></td>
</tr>
<tr>
<td>consumption</td>
<td></td>
</tr>
<tr>
<td>Defective restorations</td>
<td></td>
</tr>
<tr>
<td>Drug or alcohol abuse</td>
<td></td>
</tr>
<tr>
<td>Orthodontic appliances</td>
<td></td>
</tr>
<tr>
<td>Inability to perform adequate oral hygiene</td>
<td></td>
</tr>
</tbody>
</table>

Clinical examples

Clinical examples of at-risk and high-risk patients can be found below.

a. Patient with early childhood caries
b. Orthodontic patient
c. Patient with exposed roots

Courtesy of Dr. N. Sue Seale
Courtesy of Dr. Michael Florman
Courtesy of Dr. Scott Froum
Considerations for in-office and home-use fluorides

In addition to the ADA recommendations for professional fluorides, professional judgment, efficacy and safety, and other considerations contribute to the selection of in-office and home-use fluorides. These include pH, alcohol content, propensity for stain, and preferences.

**pH of topical fluorides**

The pH range of topical fluorides is approximately pH 3 – 7 (neutral). Acidulated phosphate fluoride (acidulated sodium fluoride) topicals are formulated for rapid uptake of fluoride; however, their use over time has the potential to etch and alter the surface of ceramics, resin-based composites and glass ionomers. In addition, acidulated phosphate alters the surface of titanium alloys, therefore caution is advised with respect to use of these formulations in implant patients. In patients for whom these are considerations, the use of neutral sodium fluoride products would be indicated.

**Table 9. pH of fluoride products**

<table>
<thead>
<tr>
<th>Product</th>
<th>pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.23% APF gel, foam</td>
<td>3-4</td>
</tr>
<tr>
<td>Sodium fluoride varnish, gel, foam</td>
<td>Neutral</td>
</tr>
<tr>
<td>NaF and MFP dentifrices</td>
<td>Neutral</td>
</tr>
<tr>
<td>0.4% stannous dentifrice</td>
<td>2.8-4</td>
</tr>
<tr>
<td>Sodium fluoride pastes, gels, rinses</td>
<td>Neutral</td>
</tr>
<tr>
<td>APF (Rx) paste/gel</td>
<td>5.1-5.6</td>
</tr>
<tr>
<td>Acidulated phosphate fluoride rinses</td>
<td>4</td>
</tr>
</tbody>
</table>

**Alcohol content**

While not a consideration for in-office topical fluorides or systemic fluoride, home-use fluoride rinses are available with an alcohol content range of 0 – 21.6%. Alcohol-containing rinses can result in irritation in some patients, and a drying sensation in patients with xerostomia, and should not be used by alcoholics or patients sensitive to alcohol. Rinses containing alcohol are generally not advised for use in children. The alcohol content of rinses can be found on the label, under the inactive ingredients.

**Extrinsic staining**

The potential for extrinsic staining of teeth is greater in patients with poor oral hygiene, smokers, red wine, tea and coffee drinkers, and with the use of stannous fluoride products. The staining propensity of products varies with formulation and can generally be controlled provided the patient performs excellent oral hygiene.

**Patient preferences and convenience**

Patient preference and convenience play important roles in the selection of home-use products, especially where patient compliance plays a key role. The fluoride selected must be acceptable to the patient, with pleasant taste, texture, smell and vehicle. Patient compliance must be considered with respect to frequency and regularity of use, ease of use, and length of application.
Home-use fluorides

Home-use fluorides include fluoride dentifrices as well as over-the-counter and prescription gels, pastes, and rinses.

Fluoride dentifrices

The majority of over-the-counter dentifrices available in the United States and Canada contain 1,000 – 1,100 ppm fluoride, available as sodium fluoride, sodium monofluorophosphate and stannous fluoride, and have been found to be effective with these formulations. (Table 10)

<table>
<thead>
<tr>
<th>fluoride dentifrice</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.23 – 0.24% sodium fluoride</td>
</tr>
<tr>
<td>0.76% sodium monofluorophosphate</td>
</tr>
<tr>
<td>0.4% stannous fluoride</td>
</tr>
</tbody>
</table>

Use of fluoride dentifrice twice daily provides a regular supply of fluoride that results in the presence of low levels of fluoride intra-orally on the teeth and soft tissues. It is recommended to commence use of a fluoride dentifrice in children at age 2, using only a pea-sized amount twice daily from the age of 2 and until reaching 6 years of age (due to the risk of fluorosis with excess ingestion). Children under the age of 6 should always be supervised while brushing (and may require supervision until 10 - 11 years of age), and they should expectorate and rinse after brushing with fluoride dentifrices. Extensive numbers of clinical trials on fluoride dentifrices have been conducted, documenting their anti-caries efficacy. There is strong evidence supporting their use, based on reviews by Twetman and by Topping and Assaf.47,48

Clinical efficacy

The number of clinical trials conducted using fluoride dentifrices is extensive, with clinical trials conducted throughout the world. These have demonstrated a substantial anti-caries benefit with the use of fluoride dentifrices. Early studies were conducted in urban and rural communities, in both cases demonstrating a substantial decline in caries with the use of fluoride dentifrices.49 In one meta-analysis of 70 such trials that were conducted in children age 16 and under, in controlled, blinded conditions, an average reduction of 24% in DMFS was found (21% – 28%) across the studies, and varying with caries risk levels. This caries reduction benefit was found in subjects in
fluoridated and non-fluoridated areas, with a greater caries reduction in higher risk individuals.\textsuperscript{50} Caries efficacy with use of fluoride dentifrices has been demonstrated for children, adults, coronal and root caries. A root caries reduction (DFS) of 67% was found in a one-year study with fluoride dentifrice.\textsuperscript{51} A recent study also found the addition of calcium and phosphate to a fluoride dentifrice resulted in an incremental reduction in root caries compared to the control fluoride dentifrice.\textsuperscript{52} A dose-response has also been found, with higher fluoride level dentifrices conferring greater anti-caries benefits than lower fluoride level dentifrices.\textsuperscript{53, 54} Supervised daily brushing with fluoride dentifrice in school programs has also been found to be a successful methodology for the control of caries in school-age populations, including in high-risk children.\textsuperscript{55,56,57}

EXTENSIVE NUMBERS OF CLINICAL TRIALS ON FLUORIDE DENTIFRICES HAVE BEEN CONDUCTED, DOCUMENTING THEIR EXCELLENT ANTI-CARIES EFFICACY.

**Prescription pastes/gels**

Prescription home-use 1.1% sodium fluoride, equivalent to 5,000 ppm fluoride, is available as pastes containing a mild abrasive and as gels/liquids containing no abrasive. These can also be used in mouth trays for extended at-home application. Use of 1.1% sodium fluoride gel in trays has been found to be effective as a caries preventive in head and neck radiation (high-risk) patients suffering from xerostomia.\textsuperscript{58} Patients using 5,000 ppm fluoride gels and paste should expectorate after using them, without rinsing with water.

Prescription pastes and gels are:

- Formulations containing 5,000 ppm fluoride
- Typically applied as brush-on pastes and gels
- Typically used in place of regular dentifrice
- Also available in an acidulated version (APF) targeting orthodontic patients.

In a small study on available fluoride in proximal saliva and plaque following use of 5,000 ppm paste, it was found that rinsing after brushing with the paste reduced the available fluoride 2.4-fold compared to expectorating only, underscoring the importance of following the instructions to expectorate only when using these prescription products.\textsuperscript{59}

**Clinical efficacy**

Use of 5,000 ppm fluoride has been found to be effective in reducing root caries. An early study by De Paola et al. demonstrated a 91% rate of arrestment for root caries lesions following one year of use of 1.1% sodium fluoride gel in trays.\textsuperscript{60} A second study by Baysan et al. demonstrated 57% remineralization of root caries lesions over a six-month period of use of 5,000 ppm fluoride dentifrice.\textsuperscript{61}
Fluoride rinses

Prescription and OTC fluoride rinses are available, variously utilizing sodium fluoride, acidulated phosphate fluoride and stannous fluoride. A dose-response relationship has been observed, with higher ppm fluoride rinses incrementally increasing the plaque and salivary fluoride levels. A separate 24-hour study by Zero et al. found that nighttime fluoride use resulted in extended fluoride retention in whole saliva.

**Prescription rinse: 0.2% sodium fluoride rinse**

Prescription fluoride rinses are available as 0.2% sodium fluoride, equivalent to 920 ppm fluoride. These are intended for weekly use and have been used in children over the age of six and in adults as caries preventives. Due to risk of ingestion, 0.2% sodium fluoride rinse is not intended for use in children under the age of six. The anticaries efficacy of weekly rinsing with 0.2% sodium fluoride has been demonstrated in numerous studies.

**Clinical support**

Heifetz et al. found significant reductions in caries in children using 0.2% sodium fluoride rinse. In a study by Driscoll et al., caries reduction of up to 55% was demonstrated in schoolchildren rinsing once weekly at school during a 30-month period. Seven years of rinsing weekly with 0.2% sodium fluoride rinse resulted in a 57.8% reduction in caries in the permanent dentition in another study. It was also concluded, however, that other factors contributed to the reductions, since reduced caries in the primary dentition was found that pre-dated rinsing.

**Over-the-counter rinses**

**0.05% sodium fluoride rinse**

Similar to the daily use of toothpaste, daily sodium fluoride rinsing has been shown *in vivo* to elevate salivary fluoride levels and plaque fluoride levels, an effect that disappears after ceasing to rinse daily. Children age 6 and over can use 0.05% sodium fluoride rinse daily; it is not recommended for use in children under age 6 due to the risk of ingestion.

**Clinical support**

Significant caries reductions have been observed with daily rinsing with 0.05% sodium fluoride in subjects living in areas with up to 0.3 ppm fluoride in the water. In his assessment, Ripa cited a 31% reduction in caries in non-fluoridated communities. A 48-month study in an urban geriatric population compared the use of placebo rinse,
0.05% sodium fluoride mouth rinse and APF gel twice per year plus placebo rinse. It was found that reductions in new lesions were statistically similar for the combination of APF gel plus placebo rinse and for 0.05% sodium fluoride rinse alone, while the reversal of lesions was greatest using the fluoride rinse.68 A more recent study assessed arrestment of smooth-surface carious lesions in 11 – 15-year olds with use of 0.05% sodium fluoride rinse once daily, finding an arrestment rate of 84.4%.69 Geiger et al. found reductions in white spot lesions (orthodontic decalcifications) following use of 0.05% sodium fluoride rinse during orthodontic treatment. While compliance issues in this study resulted in only 13% rinsing daily with the mouth rinse, a significant reduction in white spot lesions was found and correlated to the frequency of rinsing (daily as recommended versus less frequently).70 In reviewing the Cochrane Database clinical trials that addressed reductions in white spot lesions during fixed orthodontic appliance therapy, Benson et al. concluded that rinsing daily with 0.05% sodium fluoride rinse reduced the severity of enamel lesions adjacent to fixed appliances.71

THE ANTI-CARIES EFFICACY OF DAILY RINSING WITH 0.05% SODIUM FLUORIDE HAS BEEN DEMONSTRATED IN NUMEROUS STUDIES.

0.02% sodium fluoride rinse
Sodium fluoride rinses are available at 0.02% concentrations in the United States and Canada. These rinses should be used twice daily, given the lower concentration of fluoride, and are recommended for use in children age 6 and over. In vitro fluoride uptake studies using 0.02% sodium fluoride rinse have shown superior fluoride uptake. No clinical trials have been published using this rinse.

Acidulated phosphate fluoride/sodium fluoride rinses
Acidulated phosphate (sodium) fluoride rinses are available in 0.044% and 0.021% concentrations, both available over-the-counter. These are also intended for use in children age 6 and older and in adults. 0.044% acidulated phosphate fluoride has been recommended mainly for orthodontic patients, and its daily use is clinically supported. 0.021% acidulated sodium fluoride is available for twice daily rinsing.

Clinical efficacy
One early study (1978) showed that 0.044% acidulated phosphate fluoride rinse reduced the development of white spots in orthodontic patients by up to 58%.72

Stannous fluoride rinses
Stannous fluoride rinses at a concentration of 0.63% are available as prescription rinses, and they are then diluted to provide a 0.1% rinse. This was shown in an early study to be effective in reducing caries and inhibiting bacterial metabolism.73
Table 11. Clinical support for fluoride rinses and for 5,000 ppm fluoride gel/paste

<table>
<thead>
<tr>
<th>Study</th>
<th>Caries reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5,000 ppm (Rx) sodium fluoride</strong></td>
<td></td>
</tr>
<tr>
<td>de Paola et al.</td>
<td>Root caries, 1-year study 91% arrestment of root caries lesions</td>
</tr>
<tr>
<td>Baysan et al.</td>
<td>Root caries, 6-month study 57% remineralization of root caries lesions</td>
</tr>
<tr>
<td><strong>0.2% (Rx) sodium fluoride rinse</strong></td>
<td></td>
</tr>
<tr>
<td>Driscoll et al.</td>
<td>Schoolchildren, weekly rinsing, 30-month Up to 55% reduction</td>
</tr>
<tr>
<td>Leverett et al.</td>
<td>Weekly rinsing, 7 years 57.8% reduction permanent dentition</td>
</tr>
<tr>
<td><strong>0.05% sodium fluoride rinse</strong></td>
<td></td>
</tr>
<tr>
<td>Ripa</td>
<td>Coronal caries 31% caries reduction</td>
</tr>
<tr>
<td>Wallace et al.</td>
<td>Root caries Up to 71% reduction</td>
</tr>
<tr>
<td>Heifetz et al.</td>
<td>Coronal caries children Up to 40% reduction (permanent dentition)</td>
</tr>
<tr>
<td>Duarte et al.</td>
<td>Smooth surface, 11-15 year olds 84.4% arrestment of carious lesions</td>
</tr>
<tr>
<td><strong>0.044% APF rinse</strong></td>
<td></td>
</tr>
<tr>
<td>Hirschfield et al.</td>
<td>Orthodontic patients Up to 58% reduced development of white spots</td>
</tr>
</tbody>
</table>

Biofilm, rinsing and intra-oral fluoride

Fluoride dentifrice use has greatly contributed to caries reductions for several decades and continues to provide anti-caries benefits. The presence of moderate amounts of biofilm does not deter fluoride from reaching the tooth surface, and fluoride has been shown to penetrate through and concentrate in light biofilm layers, increasing the retention of intra-oral fluoride. 74

Considerations include the assessed compliance of the individual patient with appropriate brushing and use of a fluoride dentifrice, as well as his or her risk level. Non-compliant patients may brush inadequately or brush for an inadequate length of time,75 reducing the effectiveness of brushing and exposure to fluoride toothpaste. Post-brushing rinsing, which is standard practice for most patients, also removes fluoride that was

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**FLUORIDE DENTIFRICE USE HAS GREATLY CONTRIBUTED TO CARIES REDUCTIONS FOR SEVERAL DECADES.**

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**www.ineedce.com**
just delivered by the dentifrice and reduces the amount of intra-oral available fluoride. Although no controlled clinical trials are available on its impact, postbrushing rinsing has been shown to reduce the level of intra-oral bioavailable fluoride.\textsuperscript{76}

**POST-BRUSHING RINSING HAS BEEN SHOWN TO REDUCE THE LEVEL OF INTRA-ORAL BIOAVAILABLE FLUORIDE.**

Zamataro et al. found a 250% reduction in intra-oral bioavailable fluoride as a result of rinsing with 15 ml of water after use of a standard dentifrice containing 1,100 ppm fluoride.\textsuperscript{76} Adjunctive use of fluoride rinses has been advocated for moderate- and high-risk patients, together with routine oral hygiene procedures, to increase the amount of available fluoride and increase protection against caries.\textsuperscript{77,78} Increasing the flow rate of fluoride rinse has also been suggested as a possible mechanism to increase the amount of fluoride penetrating biofilm.\textsuperscript{79}

**ADJUNCTIVE USE OF FLUORIDE RINSES HAS BEEN ADVOCATED FOR MODERATE- AND HIGH-RISK PATIENTS.**

**Summary**

Successful fluoride preventive interventions began with the use of fluoridated water and fluoride dentifrices, and now include the use of professional topical fluorides as well as prescription pastes, gels and rinse and over-the-counter rinses. The individual patient’s risk level and age, and the product’s efficacy, clinical support and safety must be considered when determining the appropriate combination of preventives. Other factors to consider include clinician and patient preferences and the specifics of a given formulation. The use of fluorides has contributed greatly to reducing the level of caries seen in the population and continues to do so.

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1. Fluoride has been used in the United States as an anti-caries agent since the __________. 
   a. 1930s 
   b. 1940s 
   c. 1950s 
   d. none of the above

2. __________ an intentional source of systemic fluoride: 
   a. Fluoridated water is 
   b. Fluoride supplements are 
   c. Fluoridated salt is 
   d. all of the above

3. The use of fluoride supplements by pregnant women does not result in any benefit for the baby. 
   a. True 
   b. False

4. The Centers for Disease Control and Prevention (CDC) suggests that fluoride supplements be given to children living in areas with suboptimal water fluoridation who are at high risk of caries. 
   a. True 
   b. False

5. During tooth development, the cumulative ingestion of fluoride prior to pre-eruptive enamel maturation results in __________. 
   a. fluoride ions replacing hydroxyl ions 
   b. acidulated phosphate fluoride ions 
   c. the formation of fluorapatite crystals 
   d. a and c

6. Pre-eruptively, formed enamel is bathed in plasma that contains fluoride and contributes to the outer fluoride-rich layer. 
   a. True 
   b. False

7. Inadvertent ingestion of excessive amounts of fluoride during enamel development, from all sources combined, can result in fluorosis and is dependent on __________. 
   a. the dose of fluoride 
   b. the age of the child when excessive fluoride ingestion occurred 
   c. the duration of excessive fluoride ingestion 
   d. all of the above

8. Topical fluorides available include __________. 
   a. sodium fluoride and sodium monofluorophosphate 
   b. acidulated phosphate fluoride 
   c. stannous fluoride 
   d. all of the above

9. During acid attacks, subsurface dissolution occurs at pH 3.8 – 4.8. 
   a. True 
   b. False

10. Disease progression is more rapid in dentin than in enamel. 
    a. True 
    b. False

11. The anti-caries benefit derived from topical fluorides can be attributed primarily to the prevention of demineralization and the promotion of remineralization. 
    a. True 
    b. False

12. The application of high concentrations of topical fluoride results in __________. 
    a. the formation of alkali-insoluble calcium fluoride-like globules at the tooth surface 
    b. the formation of alkali-soluble calcium fluoride-like globules at the tooth surface 
    c. the formation of acid-insoluble calcium fluoride-like globules at the tooth surface 
    d. none of the above

13. Topical fluorides result in the retention of fluoride __________. 
    a. on the tooth surface 
    b. in saliva and dental plaque 
    c. on intra-oral soft tissues 
    d. all of the above

14. Topical fluoride is believed to inhibit caries activity through bacterial inhibition, in addition to inhibiting demineralization and aiding remineralization. 
    a. True 
    b. False

15. Most of the topical effect of fluoride is due to the presence of available fluoride rather than the influence of fluoride uptake during fluoride therapy (in-office or home-use). 
    a. True 
    b. False

16. Omitting plaque removal with a professional prophylaxis prior to the use of in-office topical fluorides has been found to __________. 
    a. result in no calcium fluoride-like globules being formed at the tooth surface 
    b. increase fluoride retention and the efficacy of fluoride therapy 
    c. decrease the efficacy of fluoride therapy 
    d. a and c

17. The vast majority of clinical trials, evidence-based studies and the major use worldwide of fluoride varnish is as an in-office topical fluoride for __________. 
    a. the prevention of dental caries 
    b. the relief of hypersensitivity 
    c. cavity linings 
    d. none of the above

18. Five percent sodium fluoride varnish has been found to be effective in reducing caries in __________. 
    a. the primary dentition 
    b. the permanent dentition 
    c. patients with root caries 
    d. all of the above

19. In a meta-analysis of fluoride gels, a caries reduction average of 21% was found (range of 14 – 28%) across 14 placebo-controlled studies. 
    a. True 
    b. False

20. The ADA does not recommend or endorse the use of one-minute gels, does not recommend the use of fluoride foams due to the paucity of clinical evidence, and does not recommend the use of in-office fluoride rinses. 
    a. True 
    b. False

21. In addition to the ADA recommendations for professional fluorides, professional judgment, efficacy and safety, and other considerations contribute to the selection of in-office and home-use fluorides. 
    a. True 
    b. False

22. The number of clinical trials conducted worldwide using fluoride dentifrices is extensive, and these have demonstrated a substantial anti-caries benefit with the use of fluoride dentifrices. 
    a. True 
    b. False

23. Use of 5,000 ppm fluoride prescription paste/gel has been found to be effective in reducing root caries. 
    a. True 
    b. False

24. The anticaries efficacy of weekly rinsing with 0.2% sodium fluoride has been demonstrated in numerous studies. 
    a. True 
    b. False

25. The anticaries efficacy of daily rinsing with 0.05% sodium fluoride has been demonstrated in numerous studies. 
    a. True 
    b. False

26. Sodium fluoride rinses are available at 0.02% concentrations in the United States and Canada, and these rinses __________. 
    a. should be used twice daily given the lower concentration of fluoride 
    b. have published clinical trials 
    c. as with 0.05% fluoride rinse, are recommended for use in children age 6 and over 
    d. a and c

27. Patient preference and convenience play important roles in the selection of home-use products, especially where patient compliance plays a key role. 
    a. True 
    b. False

28. Post-brushing rinsing has been shown to reduce the level of intra-oral bioavailable fluoride. 
    a. True 
    b. False

29. Adjunctive use of fluoride rinses has been advocated for __________ patients, together with routine oral hygiene procedures, to increase the amount of available fluoride and increase protection against caries. 
    a. low risk 
    b. moderate risk 
    c. high risk 
    d. b and c

30. The individual patient’s risk level and age, and the product’s efficacy, clinical support and safety must be considered when determining the appropriate combination of preventives. 
    a. True 
    b. False
Educational Objectives

1. List intentional and unintentional sources of systemic fluoride.
2. List and describe caries risk factors and the ADA recommendations for in-office topical fluorides corresponding to different risk levels.
3. List and describe the considerations involved in selecting in-office and home use topical fluorides.
4. List and describe the various home use topical fluorides available and the clinical efficacy of each.

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Please evaluate this course by responding to the following statements, using a scale of Excellent = 5 to Poor = 0.

- Objective #1: Were the individual course objectives met?
  - Objective #2: To what extent were the course objectives accomplished overall?
  - Objective #3: Please rate your personal mastery of the course objectives.
  - Objective #4: How do you rate the author's grasp of the topic?
  - Objective #5: How do you rate the instructor's effectiveness.
  - Objective #6: Was the overall administration of the course effective?
  - Objective #7: Do you feel that the references were adequate?
  - Objective #8: Would you participate in a similar program on a different topic?
  - Objective #9: How would you rate the objectives and educational methods?
  - Objective #10: Was there any subject matter you found confusing? Please describe.
  - Objective #11: If any of the continuing education questions were unclear or ambiguous, please list them.
  - Objective #12: What additional continuing dental education topics would you like to see?

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