What You Need to know about Fluorides and Fluoridation!

Topical Fluorides
Explosion in Product Choices…
“...F’s predominant effect is **topical**, and the effect depends on F being in the right amount in the right place at the right time.” (CDC, 2001)
Main Fluoride Delivery Sources

- Drinking water and food

- Fluoridated products
  - Water (~1 ppm)
  - Milk and Salt
  - Daily Supplements
    - OTC Rinses (~230 ppm)
    - RX Rinses (~900 ppm)
    - OTC Dentifrices (~1,100 ppm)
    - RX Dentifrices and Gels (~5,000 ppm)
    - In office Gels/Foams and Varnishes (~10,000 & ~22,000 ppm)
# CDC Recommendations

## TABLE 4. Quality of evidence, strength of recommendation, and target population of recommendation for each fluoride modality to prevent and control dental caries

<table>
<thead>
<tr>
<th>Modality*</th>
<th>Quality of evidence (grade)</th>
<th>Strength of recommendation (code)</th>
<th>Target population†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community water fluoridation</td>
<td>II-1</td>
<td>A</td>
<td>All areas</td>
</tr>
<tr>
<td>School water fluoridation</td>
<td>II-3</td>
<td>C</td>
<td>Rural, nonfluoridated areas</td>
</tr>
<tr>
<td>Fluoride toothpaste</td>
<td>I</td>
<td>A</td>
<td>All persons</td>
</tr>
<tr>
<td>Fluoride mouthrinse</td>
<td>I</td>
<td>A</td>
<td>High risk³</td>
</tr>
<tr>
<td>Fluoride supplements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant women</td>
<td>I</td>
<td>E</td>
<td>None</td>
</tr>
<tr>
<td>Children aged &lt;6 years</td>
<td>II-3</td>
<td>C</td>
<td>High risk</td>
</tr>
<tr>
<td>Children aged 6–16 years</td>
<td>I</td>
<td>A</td>
<td>High risk</td>
</tr>
<tr>
<td>Persons aged &gt;16 years</td>
<td>I</td>
<td>C</td>
<td>High risk</td>
</tr>
<tr>
<td>Fluoride gel</td>
<td>I</td>
<td>A</td>
<td>High risk</td>
</tr>
<tr>
<td>Fluoride varnish</td>
<td>I</td>
<td>A</td>
<td>High risk</td>
</tr>
</tbody>
</table>
**F toothpastes** (Marinho et al., 2003)

- The regular use is associated with a clear reduction (~24%) in caries increment, which may be relatively greater with higher caries experience. (*mainly from 1000-1500 ppm*)

- A greater preventive effect was found with increased F concentration and frequency of use (*not linear; limited evidence from 5000 ppm; might be more relevant for dentin*), and with supervised brushing.

- No evidence that effect was dependent on background exposure to fluoridated water.

*The Cochrane Database of Systematic Reviews, 2010*
F Mouthrinses-History

Today we have 3 main concentrations in the US

• 100 ppm (neutral and low pH)
• 226 ppm (neutral and low pH)
• 900 ppm (neutral, Rx)

Comparison with FV:

• 0.2% FMR less effective than FV (Duraphat) every 6 months - medium-risk area (Koch et al., 1979).

• FMR on the first 3 and last 3 school days every semester (1 nurses worked 4h to see 250 children) was less cost-effective than FV twice a year (2 nurses worked 4h to see 150 children) at 6-month intervals (Skold, 2005).
**F Mouthrinses**

- Mouthrinses and gels not appear to be more effective at reducing caries in children and adolescents than F toothpaste (Marinho et al., 2004; *The Cochrane Database of Systematic Reviews 2010*).

- The regular/supervised use of F mouthrinse (either 230 ppm 1-2x/day or 920 ppm/1x/week-0.2%NaF) by children is associated with a clear reduction (24-26%) in caries increment, regardless of fluoride background. (Marinho et al., 2003: *The Cochrane Database of Systematic Reviews, 2010*)

- Additional benefit of combining topical F products (e.g., mouthrinses) and daily F toothpaste is limited (~10%), except for at risk individuals (Marinho et al., 2004)

- “recommend that patients with fixed braces rinse daily with a 0.05% NaF mouthrinse” (Benson et al., *The Cochrane Database of Systematic Reviews 2006*)
~32 states still reporting FMR programs
Fluoridated In-Office Products

1. ~10,000 ppm - In office Gels/Foams/Rinses (~9,000 - ~12,300 ppm)
   a) 2% NaF (9,040 ppm)
      » Gels, Foams, Rinses
   b) 1.23% APF (12,300 ppm)
      » Gels, Foams

2. ~20,000 ppm - In office Varnishes (~22,600 ppm)
   a) Lacquers containing 5% NaF in a colophony/resin base
      » Individual dose or 10-mL tube for multiple applications
About 50% of states have initiated FV programs for high-risk children (in most states it must be applied by a health professional)
A bit of History of F Varnishes

• 1964 – Schmidt
  – To prolong the contact time, he incorporated NaF in a natural resin (Rosin, formerly known as colophony). Later it was registered as Duraphat®
  • Rosin is a solid form of resin obtained from pines and some other conifers. The fresh liquid resin is heated to volatilize the liquid terpene components (hydrocarbons)
A bit of History of F Varnishes

- 1960s - Duraphat®
- 1970s - Fluor Protector® (1% difluorsilane; base: polyurethane)
- 1980’s - Durafluor®
- Early 1990’s - Bifluorid®
- 1994 - Duraphat cleared by the FDA as a class II medical device: cavity liner and for hypersensitivity tx (some do not have approval even for this).
  - Caries prevention claim is a drug claim, therefore appropriate clinical trial evidence is needed
  - It is currently used “off label”
- 2000’s Cavity Shield®, Vanish®, EnamelPro®…. 
## Sample of FV in the US Market

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Solutions – Dentsply</td>
<td>Fluorilaq - Pascal</td>
</tr>
<tr>
<td>Duraphat – Colgate</td>
<td>Topex Durashield - Sultan</td>
</tr>
<tr>
<td>Prevident Varnish - Colgate</td>
<td>Dental Resources Varnish - Keystone</td>
</tr>
<tr>
<td>Flor-Opal Varnish – Ultradent</td>
<td>VarnishAmerica - MPL</td>
</tr>
<tr>
<td>Kolorz ClearShield – Zenith</td>
<td>Iris - Benco</td>
</tr>
<tr>
<td>Cavity Shield - 3M/Omnii</td>
<td>Massco - Eclipse</td>
</tr>
<tr>
<td>Vanish - 3M/Omnii</td>
<td>Duraflor Tubes &amp; unit dose - Medicom</td>
</tr>
<tr>
<td>Enamel Pro Varnish - Premier</td>
<td>Halo - Medicom</td>
</tr>
<tr>
<td>Fluoridex Lasting Defense - Discus</td>
<td>FlouoroDose - Centrix</td>
</tr>
</tbody>
</table>

Most of them with no evidence at all
Easiness of Use

1. Both gels/varnish are easy to apply (varnishes easier-no trays or suction, which makes them ideal for infants/toddlers)

2. Varnish lasts 1-7 days; gels 10-15min

3. Both deposit better on demineralized surfaces (use of caries active patients or groups)
Toxicity/Undesirable Side effects

1. In office Gels/Foams/Rinses (2% NaF & 1.23% APF)
   a) Very Safe for Adults (Fatal Acute Cases reported for Kids)
   b) Rinses have Higher Risk
   c) APF can damage tooth-colored restorations

2. In office Varnishes (5% NaF)
   a) Very Safe (inadvertent ingestion is less likely)
   b) Very small amount used (2.3-5mg)-ingestion over a long period- unlikely to contribute to fluorosis
   c) Occasionally allergy cases have been reported to the rosin
   d) Most Data from Duraphat
# Level of Evidence - ADA Recommendations

## Evidence-based Clinical Recommendations for Professionally Applied Topical Fluoride

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Age Category for Recall Patients</th>
<th>&lt;6 years</th>
<th>6-18 years</th>
<th>18+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Recommendation</td>
<td>Grade of Evidence</td>
<td>Strength of Recommendation</td>
</tr>
<tr>
<td>Low</td>
<td>&lt;6 years</td>
<td>May not receive additional benefit from professional topical fluoride application*</td>
<td>1a</td>
<td>B</td>
</tr>
<tr>
<td>Moderate</td>
<td>6-18 years</td>
<td>Varnish application at 6 month interval OR Fluoride gel at 6 month interval</td>
<td>1a</td>
<td>A</td>
</tr>
<tr>
<td>High</td>
<td>18+ years</td>
<td>Varnish application at 6 month interval OR Fluoride gel at 3 month interval</td>
<td>1a</td>
<td>A**</td>
</tr>
</tbody>
</table>

*ADA, August 2006*
Level of Evidence

1. In office Gels/Foams/Rinses (2% NaF & 1.23% APF)
   a) “Roughly” ~ 20% Caries Reduction in High Risk Pop
   b) Most Evidence from Gels
   c) Almost No Evidence for Rinses or Foams
   d) APF likely to be more effective [gels-APF- associated with a substantial reduction (21%) in caries increment. (Marinho et al., 2001: The Cochrane Database of Systematic Reviews, 2006)]

2. In office Varnishes (5% NaF)
   a) “Roughly” ~40% Caries Reduction in High Risk Pop [use 2-4 times/year, in permanent or primary teeth, is associated with a substantial (46% and 33%, respect) reduction in caries increment (Marinho et al., 2002: The Cochrane Database of Systematic Reviews, 2010)]
   b) Most Evidence from Duraphat
   c) No-limited Evidence on new ones (resin carriers)
• Use in caries prevention programs for **low risk** individuals and populations, especially those that use water fl and F toothpastes, is **unlikely to be cost-effective** (Marinho et al., 2004).

• ASTDD supports FV, beginning with tooth eruption, for individuals at **moderate to high risk**. (Policy Statement, 2010)

• CDA recommends targeting **high caries risk populations** (low income) and selectively applying FV only to those **individuals who have increased risk of caries**, as indicated by past or current **caries** (Azarpazhooh and Main, 2008).

• The AAPD, the USDHHS Maternal and Child Health Bureau Expert Panel, and the ADA identify **low socioeconomic status (SES)** of children under 6 as a high caries risk factor an indicator for FV to reduce caries prior to onset (2007).
Varnish Effectiveness

- Effectiveness is associated with the number of applications (repeated application)  
  *Tewari, 1990*

- Implication: < 1/year, probably waste of time

Zimmer et al., 1999  
Weintraub et al., 2006
Cost-Effectiveness

1. Cost of the material for gels/varnish groups is relatively inexpensive

2. Cost of personnel to apply them (use personnel already involved in other programs)

3. Cost-effective if used in High Risk CARIES ACTIVE patients (assess community: low SES, caries experience)

Cost-effectiveness of FV in pediatric settings during regular well-child visits at 9, 15, 24, and 36 months of age (Quiñonez et al., 2006):

- From a Medicaid’s perspective, FV showed only modest improvement in outcome (2 additional months in a cavity-free state between 9-42 months of age, i.e., $278 per case of treatment averted)….thus the program was expensive.
- Is it feasible to have pediatricians apply FV to all Medicaid children or should selected groups be targeted (need for a CRA tool)?
Are They All the Same?

We do not know!

US Regulation

- FDA (medical device)
- ADA and ISO (developing standard-not for efficacy)
Summary

• F varnish as prepared for Duraphat is clinically effective in caries management and prevention
  – Limited understanding of its MOA
• Clinical or laboratory efficacy for most of today’s products is unknown
• Therefore, program outcomes are critical to evaluate different products/protocols for use in public health settings
Thank you...