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**Clinical practice recommendations for non fluoride anticiaries products: review and summary**

Frieda A. Pickett, RDH, MS

**ABSTRACT**

Objective: The American Dental Association Council on Scientific Affairs selected an expert panel to review the science regarding efficacy for non fluoride anticiaries products and to assist practitioners with decisions on the use of non fluoride caries preventive agents to arrest, prevent or reverse caries. The purpose of this paper is to review and summarize the most important aspects of the panel’s report. Methods: The expert panel conducted a systematic review of the literature to answer the following clinical questions: 1. In the general population, does the use of a non fluoride caries preventive agent reduce the incidence, arrest or reverse caries? 2. In individuals at higher caries risk, does the use of a non fluoride caries preventive agent reduce incidence, arrest or reverse caries? Findings: The majority of non fluoride agents—xylitol, chlorhexidine, amorphous calcium or casein derivatives, etc.—have weak evidence as anticiaries agents and most were not recommended for use. Those recommended were to be used as adjuncts in individuals at high risk of developing caries. Conclusion: Only one product, chlorhexidine/thymol varnish, received a recommendation for reducing root caries. One product was graded as having weak evidence for implementation—sucrose free polyol—xylitol only or polyol combinations chewing gum—for coronal caries reduction. The panel strongly recommended that practitioners first implement evidence based anticiaries products or practices—fluoride, sealants, dietary practices limiting sugar consumption—before attempting to use non fluoride adjunctive therapies.

**RESUMÉ**


**Key words: caries, preventive dentistry, non fluoride caries prevention**

**INTRODUCTION**

A standard of care for health professions is to develop clinical practice guidelines based on the most reliable science. As well, health professionals must develop skills as scientists to identify reliable study designs and correctly interpret data presented within studies. In addition, oral health professionals must be aware that product claims may not represent product efficacy.1 The current trend is to be aware of best practices for intraoral procedures for delivery of optimal clinical care to clients. Clients expect the clinician to be aware of new therapies with improved outcomes when compared to older, traditional therapies,1 to offer effective treatment options, and to consider the financial burden to the client. Information changes over the years and new evidence based treatment options must be considered. The systematic review (SR) is the highest level of evidence for scientific investigation.2 The American Dental Association, Council on Scientific Affairs formed an expert panel of eighteen researchers and clinicians to conduct an SR to evaluate the evidence regarding non fluoride products available in the United States, promoted to have an anticiaries effect.3 The panel’s report was further reviewed by twenty one additional scientists, policy experts and committees.4 The panel evaluated studies of sucrose free polyol chewing gums, xylitol dentifrices, chlorhexidine, chlorhexidine in combination with thymol, calcium containing agents, casein derivatives, phosphoric acid containing agents, fluoride, sealants, xylitol systemic tablets or the like. This panel presented evidence based clinical recommendations5 for products, but stipulated they be used as adjuncts to primary anticiaries
Short Communication – Pickett

Non fluoride anticaries products

**Polysaccharide gums**

Four studies were selected evaluating the effects of xylitol in candy, lozenges, and tablets, and one study evaluating the effects of xylitol syrup on root caries.

Xylitol dentifrice

Two large scale RCTs comparing 10 percent xylitol in fluoride dentifrice with fluoride dentifrices without xylitol were identified.

**Antibacterial agents (triclosan and iodine)**

The panel found no published literature evaluating the effects of triclosan alone on caries prevention. Therefore, the panel concluded there is insufficient evidence that triclosan lowers incidence of caries.

Iodine reduces *Streptococcus mutans* concentrations in vitro and in vivo. One study evaluated 10 percent povidone–iodine on coronal caries in pre school and school aged children. Three studies assessed caries using a visual examination. One study used laser fluorescence for diagnosis and reported quantitative laser fluorescence scores. Two studies were judged to be of fair quality and two studies of good quality. All studies were relatively small. Combining the studies was impossible because of differences in outcome measures reported in the studies. The panel concluded, "There is insufficient evidence that use of iodine lowers incidence of caries." 4

**Topical chlorhexidine (CHX) products**

Remineralization of demineralized enamel has been suggested by several clinical trials comparing chlorhexidine/ phosphorous products or casein derivatives. The panel identified nine studies, eight of which were RCTs, comparing products containing calcium/phosphorous or casein derivatives with and without casein derivatives. Two of these were judged to be of good quality; five were judged to be of fair quality and the others were deemed poor in quality. Comparison groups were varied, as were formulations such as dentifrice, rinses, and chewing gum. Both caries and white spot lesions were assessed in studies. Although the panel found several studies on calcium and phosphate agents with and without casein derivatives, the differences in composition of the products, their varying delivery mechanisms, differing study designs and the varied results made determination of efficacy for each agent difficult. The panel was unable to group them into an

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**METHODS**

The systematic review included an evidence summary for 66 studies, whose authors described 51 randomized controlled trials (RCTs) and 15 non randomized studies assessing the efficacy of various non fluoride caries preventive agents. Most studies were conducted in communities with low levels of fluoride in the water supplies. Only a few studies were conducted in communities with high levels of fluoride. All types of polyols were included in the analysis. The studies comparing agents with a combination of polyols. One SR reported the total grams of xylitol consumed per day influenced caries prevention. Significant statistical heterogeneity (P > .05%) was found among studies included in the MA, confirming clinical and methodological differences. It is biologically plausible that the act of chewing and the production of increased salivation could be responsible for the beneficial effects reported. Since all studies had the "no gum" comparison, the effect of salivary stimulation from chewing was unknown. The low quality of most studies limited the panel's confidence in the observed results; however the number of studies showing a consistent preventive effect led the majority of the expert panel to conclude that chewing gum with xylitol has an important role in caries prevention. In conclusion, xylitol gum had the highest caries reduction, followed by gums with a combination of polyols. One SR reported a statistically significant anticaries effect for children aged 2 or younger. However, since only one study was found the panel concluded, "There is insufficient evidence that xylitol syrup prevents caries in children under 2 years of age." 4 A conclusion of "insufficient" evidence does not mean that the intervention is ineffective, but rather that not enough evidence exists to support a recommendation.

**Table 1. Summary of recommendations from American Dental Association expert panel for non fluoride caries preventive agents**

<table>
<thead>
<tr>
<th>Non fluoride Anticaries Product</th>
<th>Recommendation</th>
<th>Strength of recommendation</th>
<th>Expert opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose free polyol gum (xylitol, sorbitol)</td>
<td>Coronal caries: Children 5 years or older</td>
<td>Strong</td>
<td>Moderate certainty</td>
</tr>
<tr>
<td></td>
<td>Chewing gum for 10 to 20 minutes after meals</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sucrose free xylitol containing lozenges, candy, mint</td>
<td>Coronal caries: Children 5 years or older</td>
<td>Strong</td>
<td>Moderate certainty</td>
</tr>
<tr>
<td></td>
<td>Chewing gum for 10 to 20 minutes after meals</td>
<td></td>
<td></td>
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<tr>
<td></td>
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</tr>
<tr>
<td>Chlorhexidine/ thymol varnish</td>
<td>Root caries: elderly, adults; 1:5 mixture of chlorhexidine/thymol varnish, applied every 3 months</td>
<td>Moderate</td>
<td></td>
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<td></td>
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</tbody>
</table>

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**Primary anticaries strategies**

An important component of the SR was the recognition of reliable evidence supporting products or dietary changes that prevent or ameliorate caries outcomes. The report began with the statements, “The use of fluoridated toothpastes, other topically applied fluorides, fluoridated gels and rinses for anticaries effects. Table 2 summarizes the results of this review of twenty seven studies. A 10 percent CHX varnish is approved as a prescription drug by Health Canada for “the reduction of root caries in adults at high risk of root caries” in application for approval by the Food and Drug Administration in the USA has been submitted but no action has been taken at this time.

**Calcium, phosphorous, casein derivative agents**

Remineralization of demineralized enamel has been suggested by several clinical trials comparing chloride/ phosphorous products or casein derivatives. The panel identified nine studies, eight of which were RCTs, comparing products containing calcium/phosphorous or casein derivatives with and without casein derivatives. Two of these were judged to be of good quality; five were judged to be of fair quality and the others were deemed poor in quality. Comparison groups were varied, as were formulations such as dentifrice, rinses, and chewing gum. Both caries and white spot lesions were assessed in studies. Although the panel found several studies on calcium and phosphate agents with and without casein derivatives, the differences in composition of the products, their varying delivery mechanisms, differing study designs and the varied results made determination of efficacy for each agent difficult. The panel was unable to group them into an
Table 2: Topical chlorhexidine (CHX) products (27 studies)

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Quality of RCTs</th>
<th>Meta analysis: Non significant difference of 10-40% between CHX and placebo varnish</th>
<th>Conclusion: Moderate certainty</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHX varnish</td>
<td>Good=1, Fair=2</td>
<td>Poor=1. And 1 ongoing RCT may provide additional evidence.</td>
<td>CHX rinse prevents the incidence of coronal caries.</td>
<td></td>
</tr>
<tr>
<td>CHX/thymol varnish</td>
<td>Good=2, Fair=3</td>
<td>This also used sodium fluoride varnish compared to a fluoride varnish alone.</td>
<td>Conclusion: Moderate certainty in children aged 13 to 15 years, application of a 1:1 mixture of chlorhexidine/thymol varnish reduces the incidence of root caries.</td>
<td></td>
</tr>
<tr>
<td>Mouthrinses: CHX/menthol varnish</td>
<td>Good=3, Fair=1</td>
<td>Poor=5</td>
<td>Conclusion: High certainty in children aged 13 to 15 years, application of a 1:1 mixture of chlorhexidine/thymol varnish reduces the incidence of root caries.</td>
<td></td>
</tr>
<tr>
<td>Gels using 1% CHX: 7 clinical studies, no meta analysis</td>
<td>Good=3, Fair=1</td>
<td>Poor=2</td>
<td>Limitations of studies: differences among studies - small numbers of study subjects - limited number of studies - inconsistency in results</td>
<td></td>
</tr>
</tbody>
</table>

MA. The panel concluded, "There is insufficient evidence from clinical trials that use of agents containing calcium and/or phosphates with or without casein derivatives lowers incidence of either coronal or root caries." Mother to child transmission of caries promoting factors Four studies evaluated the use of caries preventive agents in mothers aimed at positively affecting the caries incidence of children. One RCT evaluated 10 percent CHX gel and reported a statistically significant reduction in caries experience. The study concluded that the reduction in caries with calcium supplementation in mothers and its effect on children. Authors reported a 27 percent reduction in risk of developing caries. Two studies were judged to be of fair quality while the other two were of poor quality. Based on these four trials which were conducted on different agents, the panel concluded, "There is insufficient evidence that use of xylitol gum, chlorhexidine varnish or gel or calcium supplementation in mothers lowers incidence of caries in children." The panel noted that pregnant women were not included in any of the studies for non fluoridated products, so products have not been shown to be safe for this population.

CONCLUSION
The panel reported weak evidence for sucrose free polyol chewing gum to be recommended to parents and caregivers of children ≤ 5 years old for coronal caries prevention. Xylitol only gum or polyol combinations were recommended for use of xylitol candy or hard candies in adults and children ≥ 5 years. If xylitol hard candy or mints is advised, the patient should be told to consume 5 to 8 grams divided into 2 or 3 doses each day. The panel found insufficient evidence to recommend xylitol syrup, xylitol in dentifrices, triclosan, iodine, salogogues, and calcium phosphate/ACP or casein derivative products for caries prevention. None of the non fluoridated agents should be advised for use in pregnant mothers as agents have not been studied in this group.

Evidence was weak, however in the office application of 1:1 mixture of chlorhexidine/thymol varnish was recommended every three months for the reduction of root caries, but not for coronal caries. Other forms of CHX = 0.5 to 1% CHX gel or CHX gel combined with fluoride were not recommended for root caries prevention, and neither were 0.12 percent CHX rinses, alone or in combination with fluoride. No CHX product was recommended for coronal caries prevention.

REFERENCES