

Evidence based technical document for fluoride varnish application

Designed to Smile, as announced by the Minister for Health and Social Services in April 2008, forms a key element of the oral health improvement agenda in Wales.

The core programme comprises two parts, the supervised toothbrushing scheme for 3-5 year olds and a promotional programme for 6-11 year olds. The core programme also includes the clinically appropriate use of other fluoride supplements.

This document reviews the evidence for the use of fluoride varnishes as a supplement to the toothpaste/tooth brushing programme in Wales. The classification of evidence and grades of recommendation are based on those used by the journal for Evidence Based Dentistry (Appendix A).

Recommendations

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| Children between the ages of 3 of 16 should be eligible for fluoride varnish | Grade A |
| Children from the ages of 6 months to 3 years who have a high risk of caries should be considered for fluoride varnish applications | Grade A* |
| Children at high risk of dental caries or from high risk areas are advised to have topical fluoride varnish applications 2-4 times per year at regular intervals of 6 months or less | Grade A |
| Fluoride varnish needs to be delivered through a programme that encourages the participation of children from high caries risk groups | Grade B |

The papers have been divided into areas of; fluoride varnish, fluoride varnish as a supplement to fluoride toothpaste, the concentration and dose of fluoride varnish preparations, frequency of application, fluoride varnish in high and low risk populations and programmes for the delivery of fluoride varnishes.

Results from the studies reviewed provide evidence that:

1. Fluoride varnishes are effective in inhibiting caries.
2. Fluoride varnishes are effective in children from the ages of 3 to 16 years.
3. There is a small but inconclusive amount of evidence suggesting that children aged from 6 months in high risk groups would benefit from fluoride varnish applications.
4. Fluoride varnish techniques are quick and acceptable to young patients.
5. Application of fluoride varnish for low risk populations at regular 6 monthly intervals would prevent caries in the population.
6. Application of fluoride varnishes for high risk populations at regular intervals of 4-6 months would prevent approximately 66-69% of carious surfaces.
7. The most effective and tested concentration of fluoride varnish preparation is 22,600 ppm F⁻ (2.2%F⁻).

For young children below the age of 3, there was only a small amount of evidence to support the use of fluoride varnishes.¹ The lack of evidence in this area does not demonstrate fluoride varnishes are not potentially appropriate or effective in the prevention of caries.

There are different definitions in studies for the risk of dental caries, with some studies using a child's individual caries history as the indicator of risk and other studies using area based measures, area DMFT and economic deprivation. Few studies compared the effects on fluoride varnish on children with differing levels of risk. However there is a trend towards an increased preventative effect in high risk populations.

Studies have most frequently measured the mean number of carious surfaces in first permanent molar teeth. The overall effects of fluoride varnish application on the other teeth in the dentition have been subject to less research.

There is limited evidence comparing community based programmes to deliver fluoride varnish. Non responses, lack of consent and drop out rates have affected most studies of fluoride varnishes. Analysis of non responders has shown that this population is the most likely to have untreated dental caries², therefore prevention programmes should aim to encourage participation from these groups.

Fluoride varnishes are not suitable for all children as they are contraindicated in children with ulcerative gingivitis and stomatitis.³ Children with a history of hospital admissions for allergic episodes should not have varnish application as the preparation Duraphat contains colophony (roisin), which can cause allergy in a small number of children.³

¹ SIGN 83: Prevention and management of dental decay in the pre-school child. November 2005.

² Splieth, C. H. et al. 2005. Responder and nonresponder analysis for a caries prevention program. *Caries Research* 39(4), pp. 269-272.

³ Delivering better oral health. An evidence based toolkit for prevention. Department of Health, England 2007.

| Subject area | Evidence | Source | Level of evidence |
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| Fluoride varnish | <p>In a systematic review of fluoride varnishes 9 studies were included (involving 2709 children) of which 7 studies contributed to a meta analysis. A mean of 33% fewer surfaces with caries in the primary dentition and 46% fewer carious surfaces in the adult dentition was seen in the population of children treated with fluoride varnishes compared to those with no treatment.</p> <p>Twenty four trials including over 12,000 children were included in a systematic review of the use of fluoride varnishes in children. Children receiving fluoride varnish had a mean of 30% fewer carious surfaces in permanent molars compared to a placebo or no treatment. Children treated with fluoride varnish had 17.8% fewer carious surfaces than active controls treated with other fluoride treatments. In addition three trials compared the effects of fluoride varnish on the deciduous dentition of young children. One of the three studies found a mean of 44% fewer surfaces with caries in the population treated with fluoride varnish, while the other 2 studies did not have significant results.</p> <p>A systematic review of Duraphat fluoride varnish for the prevention of caries included a meta analysis including 8 studies involving 927 children. The population treated with fluoride varnish had a mean of 38% fewer carious tooth surfaces than untreated controls.</p> <p>A systematic review of the literature identified 7 studies of fluoride varnish use in the deciduous dentition, of which only two were randomised controlled trials. The incidence of carious surfaces was lower in population treated with fluoride varnish in the studies, but the findings were statistically insignificant in 5 of the 7 studies.</p> | <p>Marinho VCC, Higgins JPT, Logan S, Sheiham A. Fluoride varnishes for preventing dental caries in children and adolescents. <i>Cochrane Database of Systematic Reviews</i> 2002, Issue 1. Art. No.: CD 002279. DOI: 10.1002/14651858.CD002279.</p> <p>Petersson LG, Twetman S, Dahlgren H, Norlund A, Holm AK, Nordenram G, et al. Professional fluoride varnish treatment for caries control: a systematic review of clinical trials. <i>Acta Odontol Scand.</i> 2004 Jun;62(3):170-6.</p> <p>Helpfenstein U, Steiner M.1994. Fluoride varnishes (Duraphat): a meta-analysis. <i>Community Dentistry & Oral Epidemiology</i> 22(1), pp. 1-5.</p> <p>Rozier, R. G. and Rozier, R. G. 2001. Effectiveness of methods used by dental professionals for the primary prevention of dental caries. <i>Journal of Dental Education</i> 65(10), pp. 1063-1072.</p> | <p>1a</p> <p>1b</p> <p>1a</p> <p>1b</p> |

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| | <p>A randomised controlled single blind trial including 376 children at enrolment tested the effect of applying fluoride varnish to children who were between the ages of 6 and 44 months at the start of the study. Despite errors in the allocation of fluoride varnishes, children who did not have fluoride varnish treatment had 50% more carious surfaces than the population treated with fluoride varnishes. The children treated more frequently, with up to 4 applications of with fluoride in a year had fewer new carious lesions.</p> | <p>Weintraub, J. A. et al. 2006. Fluoride varnish efficacy in preventing early childhood caries. <i>Journal of Dental Research</i> 85(2), pp. 172-176.</p> | <p>1b</p> |
| <p>Fluoride varnish to supplement fluoride toothpaste</p> | <p>One systematic review identified two studies comparing the combination of fluoride varnish and fluoridated toothpaste with toothpaste alone. One of the trials included compared the effects of combined therapy (toothpaste and fluoride varnish) on the percentage of new carious surfaces in permanent teeth, with the population treated with varnish showing 48% fewer carious surfaces. The second study showed that combined therapy prevented 15% of carious surfaces in the deciduous dentition compared to toothpaste alone.</p> <p>A systematic review included a meta analysis of 4 studies involving a total of 924 children; these studies compared fluoride varnish and other fluoride delivery systems as controls. The results indicated that fluoride varnish had a positive effect on caries, with all but one of the studies demonstrating positive findings but the study findings were not statistically significant.</p> | <p>Marinho VCC, Higgins JPT, Sheiham A, Logan S. Combinations of topical fluoride (toothpastes, mouthrinses, gels, varnishes) versus single topical fluoride for preventing dental caries in children and adolescents. <i>Cochrane Database of Systematic Reviews</i> 2004, Issue 1. Art. No.:CD002781. DOI: 10.1002/14651858.CD002781.pub2.</p> <p>Strohmeinger L, Brambilla E. 2001. The use of fluoride varnishes in the prevention of dental caries: a short review. <i>Oral Diseases</i>. 7: 71–80.</p> | <p>1a</p> <p>1a</p> |
| <p>Concentration and dose of fluoride varnish</p> | <p>There was no conclusive evidence identifying the most effective concentration of fluoride varnish preparation. However one systematic review noted that the most frequently used concentration in studies used to demonstrate the effectiveness of fluoride varnish was 22,600 (2.2%F).</p> | <p>Azarpazhooh, A. Main, PA. 2008. Fluoride varnish in the prevention of dental caries in children and adolescents: a systematic review.[reprint in <i>Tex Dent J</i>. 2008 Apr;125(4):318-37; PMID: 18491761]. <i>Journal (Canadian Dental Association)</i> 74(1), pp. 73-79.</p> | <p>1b</p> |

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| | A systematic review of fluoride varnishes included 3 studies that found single dose vials provided a more consistent dose of fluoride than multidose vials, though no optimum dose was specified. | Azarpazhooh, A. Main, PA. 2008. Fluoride varnish in the prevention of dental caries in children and adolescents: a systematic review.[reprint in <i>Tex Dent J</i> . 2008 Apr;125(4):318-37; PMID: 18491761]. <i>Journal (Canadian Dental Association)</i> 74(1), pp. 73-79 | lb |
| Frequency of application | <p>A systematic review of fluoride varnishes detailed the findings of the 7 articles meeting the inclusion criteria. This concluded that regular fluoride varnish application 2-4 times per year in the deciduous and permanent dentition prevents caries in children.</p> <p>One randomised controlled trial compared different regimes for the application for fluoride varnishes. Fluoride varnish applied monthly prevented 76% of caries, whilst the 6 monthly application of varnish prevented 57% of carious surfaces across all of the populations.</p> | <p>Marinho VCC, Higgins JPT, Logan S, Sheiham A. Fluoride varnishes for preventing dental caries in children and adolescents. <i>Cochrane Database of Systematic Reviews</i> 2002, Issue 1. Art. No.: CD 002279. DOI: 10.1002/14651858.CD002279.</p> <p>Skold UM, Petersson LG, Lith A, Birkhead D. 2005. Effect of School-Based Fluoride Varnish Programmes on Approximal Caries in Adolescents from Different Caries Risk Areas. <i>Caries Research</i> 39, pp. 273-279.</p> | lb la |
| Fluoride varnish for prevention in high and low risk populations | In one randomised controlled trial, there was a greater percentage of caries prevented in children living in areas with a high risk of caries. Children from high risk areas treated with fluoride varnish had 69% fewer carious surfaces, compared to no varnish treatment, whereas there was a 20% reduction in the caries in the population treated with fluoride varnish from a low risk area. | Skold UM, Petersson LG, Lith A, Birkhead D. Effect of School-Based Fluoride Varnish Programmes on Approximal Caries in Adolescents from Different Caries Risk Areas. <i>Caries Research</i> 39, pp. 273-279. | lb |
| Acceptability of Fluoride varnish | A controlled trial compared the acceptability of professionally applied fluoride delivery systems and concluded that fluoride varnish was a faster procedure than other methods and patients found this technique more acceptable. | Hawkins R, Noble J, Locker D, Weibe D, Murray H, Weibe P, Frosina C, Clarke M. A comparison of the costs and patient acceptability of professionally applied topical fluoride foam and varnish. <i>Journal of Public Health Dentistry</i> 64(2), pp. 106-110. | lla |

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| | A randomised controlled trial applying fluoride varnish of very young children's teeth, Starting with children aged 6-44 months, they reported little difficulty with co operation in this population. | Weintraub, J. A. et al. 2006. Fluoride varnish efficacy in preventing early childhood caries. <i>Journal of Dental Research</i> 85(2), pp. 172-176. | lb |
| Fluoride varnish programmes | <p>Cluster Randomised controlled trial of a fluoride varnish programme involved 334 children aged 6-7 in the test group and 330 in the control group in 32 schools. The study, which involved the application in fluoride varnish to children in school found significantly fewer enamel lesions in the treatment group but did not find a significant reduction in caries in the children receiving varnish. The lack of significance was attributed to the population with the greatest likelihood of decay and subsequent potential for prevention not consenting to participate.</p> <p>A cross sectional study was used to evaluate the effectiveness of a caries prevention programme in Germany. Alongside tooth brushing and oral health education this programme included fluoride varnishes. Continual decreases in the population mean DMFT for school children of all ages was observed year on year.</p> | <p>Hardman, MC. Davies, GM. Duxbury, JT .Davies, RM. 2007. A cluster randomised controlled trial to evaluate the effectiveness of fluoride varnish as a public health measure to reduce caries in children. <i>Caries Research</i> 41(5), pp. 371-376.</p> <p>Dohnke-Hohrmann, S. Zimmer, S. et al. 2004. Change in caries prevalence after implementation of a fluoride varnish program. <i>Journal of Public Health Dentistry</i> 64(2), pp. 96-100.</p> | <p>lb</p> <p>III</p> |

Appendix A

Classification of evidence levels and grades of recommendations

| Evidence level | Required standard |
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| Ia | Evidence obtained from meta-analysis of RCT |
| Ib | Evidence obtained from at least one RCT |
| IIa | Evidence obtained from at least one well-designed controlled study without randomisation |
| IIb | Evidence obtained from at least one other type of well-designed quasi-experimental study |
| III | Evidence obtained from well-designed nonexperimental descriptive studies, eg, comparative studies, correlation studies and case studies |
| IV | Evidence obtained from expert committee reports or opinions and/ or clinical experiences of respected authorities |
| Grades of recommendations | |
| A | Requires at least one RCT as part of a body of literature of overall good quality and consistency addressing specific recommendation (evidence levels Ia, Ib) |
| B | Requires availability of well-conducted clinical studies but no RCT on topic of recommendation (evidence levels IIa, IIb, III) |
| C | Requires evidence obtained from expert committee reports or opinions and/ or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV) |

* A situation in which implementation of an intervention is beyond the control of the investigators, but an opportunity exists to evaluate its effect.
RCT, Randomised controlled trial.

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