EVIDENCE-BASED RECOMMENDATIONS FOR THE USE OF PROFESSIONALLY APPLIED TOPICAL FLUORIDES IN THE NORTH YORK PUBLIC DENTAL PROGRAM

An Evidence-based Report

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Evidence-based Recommendations

for the Use of Professionally Applied Topical Fluorides

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1.0 The context for evidence-based recommendations

The North York area of the new City of Toronto is a multi-cultural area of over 540,000 people. Thirty-eight per cent (38%) of children in the North York area report they were born outside Canada. In Ontario, the children born outside Canada are 2.5 times more likely to have experienced dental decay and 2.2 times more likely to have urgent need for care. High levels of dental decay and unmet urgent needs also are common to families living in poverty who often seek care from the public health department. Dental diseases are concentrated in a minority of the population. For example, at age 13, 78% of caries is found in 25% of the North York child population.

The Toronto Public Health, North York Office (formerly North York Public Health Department) has provided dental treatment to children since 1939. Since then, clinical and community-based preventive services, such as fluorides and education, have been added.

Each year the program is allocated a fixed budget from which all program costs must be met. The program operates with core values of:

- Population health - doing the greatest good for the greatest number so as to make a measurable difference to the target population's health
- Prevention - health promotion and primary prevention strategies are favoured over treatment and rehabilitation

- Evidence-based care - scientific evidence of need and the effects of intervention will guide the provision of care; where evidence is lacking, studies may be mounted to develop that evidence

- Equity - care will be allocated directly in proportion to need with urgent and basic needs having priority

- Ethics - the program will adhere to ethical principles of autonomy, non-maleficence, beneficence, justice and collegiality and will be open it its resolution where these principles conflict.

Program guidelines have been developed to assist clinicians in making decisions on the management of patient care. The guidelines and the underlying evidence-based report also assist managers to: i) allocate resources to achieve maximum impact, and ii) to assure the quality of patient care.

2.0   The need to examine professionally applied topical fluorides

Given that topical fluorides are often used in the prevention of dental caries and their application represents a major commitment of staff time, the evidence supporting, and the recommendations to guide their use, were examined in 1995 (Woodward and Lewis). That report, 'Use of Professionally Applied Topical Fluorides in the North York Community Dental Services', was based on the evidence available before 1992. Since then, additional clinical studies have been reported in the scientific literature. This report provides an update to the 1995 report.

Since the 1995 report, the six municipalities in Metropolitan Toronto have been

amalgamated into a unified city, Toronto. The former North York Public Health Department is now part of the new city's public health services and the geographic area of the former North York roughly corresponds to the northern health region in the new city. However, given that the report was developed for the former North York Health Department, references to the former North Community Dental Services will be maintained.

The purpose of this review is to summarize the scientific evidence on professionally applied topical fluoride (PATF) and to make recommendations on the appropriate use of PATF, which flow from that evidence, for the former North York Community Dental Services (NYCDS). The review began in early 1997 and therefore covers the information that was available up until November, 1996.

3.0   Structure of this report

The organisation of this review follows the template proposed at the RCDSO/CDHSRU workshop on developing clinical guidelines/standards of practice (Leake et al., 1996). The template outlines that reports be organised under the following headings:

1. Target population
2. Clinical problem
3. Clinical flexibility
4. Summary of evidence
5. Comparison of costs
6. Relative importance of the potential outcomes

7. Evidence-based recommendations and minority views

8. Comments and suggestions for further research

4.0 Target population

4.1 Patient Populations Included

These guidelines apply to children who receive dental care from the North York Community Dental Services (NYCDS). North York has a large number of clients from families recently immigrated to Canada. Many of these children have never been exposed to fluoridated water and, on average, they have higher numbers of teeth affected by decay.

4.2 Patient Populations Excluded

These guidelines do not apply to adults or seniors who are not treated in the NYCDS.

5.0 Clinical problem

The question addressed in this review is: What is the appropriate use of PATF in the prevention of dental caries? Specifically we want to answer:

i) Which PATF therapies should be used?

Common PATF therapies will be evaluated in terms of the:

- expected benefits;

- potential harmful effects;.

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- ease of application; and

- expected implementation and operating costs

ii) What procedure should be followed when using the PATF therapies, namely:

- who should receive PATF?

- how often should a child receive PATF?

- is a professional cleaning needed before PATF?

- should a cleaning be followed by a PATF, even if the child is not at high caries risk?

- how much fluoride should be applied to a child's teeth and what general procedure should be used? and

- how long should the fluoride preparation be retained in the mouth?

5.1 Prevalence of Dental Caries

Caries prevalence among children in western countries fell substantially during the 1970s and 1980s (Tubert-Jeannin et al., 1993; Anderson, 1995). Some epidemiological studies have shown that the secular trend in caries prevalence may have flattened out in the primary dentition, while the downward trend has continued among those 12-years and above (Truin et al., 1993; ORCA Saturday Afternoon Symposium, 1995). In the United States, a national survey conducted in 1986-87 reported that 50% of the schoolchildren (5-17 years) were caries free, compared to 37% in 1979-80 (Newbrun, 1989; Ripa, 1991).

In Ontario, 68% of children aged 5 had no history of decay (deft + DMFT = 0) in 1994, compared to 42% in 1972 (Leake and Main, 1995). The percentage of 13-year-olds who were caries-free rose from 8% to 52% between 1972 to 1994. Over the same period, the mean caries scores for the 5-year-olds and the 13-year-olds fell from 2.47 to 1.23 deft and from 5.3 to 1.46 DMFT, respectively.

However, not all children experience the same degree of reduction in caries risk and dental caries remains a significant problem in a small group of high-risk children. In the United States, a survey for the National Preventive Dentistry Demonstration Program found that 20% of the children accounted for nearly 60% of the total DMFS score (Bohannan et al., 1985). In Ontario, 52.4% of children born in Canada were caries free, compared with 37.6% of those who were born elsewhere (Leake and Main, 1995).

The decline in the prevalence of dental caries has not been uniform across all tooth surfaces. On a percentage reduction basis, the prevalence of occlusal lesions has declined less than lesions on other tooth surfaces. Hence, they make up an even higher proportion of the burden of dental caries. For example, among 5-to-17-year-olds in the United States, occlusal lesions accounted for 89% of dental caries in 1987, compared to 84% in 1979-80 (Li et al., 1993) - see Table 1 - and 49% in 1971-73 (Bohannan, 1984).

As seen in Table 1, even though the greatest absolute decline in caries risk was observed among the pit and fissure surfaces, 55.53 per 1,000 surfaces at risk, the percentage decline compared to other surfaces and teeth was lowest, 31%. Hence, pit and fissure caries have become even more prominent.

Canadian data are available from a study of 6-to-14-year-olds in British Columbia and are

shown in Table 2 (Clark et al., 1995). Pit and fissure caries accounted for 77% and 74% of all caries lesions in children with and without a lifelong fluoridation history, respectively.

The high prevalence of pit and fissure caries may have important implications on the overall effectiveness of PATF. In terms of relative reduction in DMFS, PATF is more effective against smooth surface caries than against pit and fissure caries (Woodward and Lewis, 1995). However, given the prominence of pit and fissure caries the absolute effectiveness of PATF needs to be carefully examined.

6.0   Clinical flexibility

These guidelines do not apply to children who are unable tolerate the procedure because of gag-reflex or medical problems. The guidelines may also not apply to children who are believed to be at much higher risk of caries due to a physical or other handicap. This guideline does not address the prevention and management of early enamel caries through other technologies, e.g. diet counselling, nor the management of the later stages of the disease when a restoration would ordinarily be required. Individuals may refuse to receive PATF as recommended under these guidelines.

7.0   Evidence for efficacy of PATF

7.1   Search Strategy

The search for scientific evidence on the research questions involved a three-stage process. First, we conducted computerized literature searches on Medline <1992 to November 1996> with the following search strategies:

1.   Textword = topical fluorides

   or textword = topical fluoride

   or textword = professionally applied fluorides

   or textword = professionally applied fluoride

   Yield = 52 articles

2.   Subject heading = topical fluorides

   Yield = 78 articles

3.   The two set of references 1 & 2 were combined.

   Yield = 108 articles

At the second stage, the authors screened the abstracts of the 108 papers to identify those which might yield scientific evidence relevant to the research questions. Fifty-three articles were selected by at least one author. Of these, 48 were available from the libraries at the North York Public Health Department or the Faculty of Dentistry, University of Toronto. Another three articles on the systemic use of fluorides, which were part of the series on fluoride published in the 1993; 27 (Supplement) issue of Caries Research, were also obtained.

The authors reviewed all 51 articles to obtain the evidence for this review.

7.2 Inclusion/Exclusion Criteria

At the first stage , we selected only those papers which involved human subjects and were written in English. At the second and third stages we ranked the studies according to the level of evidence and the five-category classification of recommendation system developed by the Canadian Task Force on the Periodic Health Examination (CTFPHE) (1994). We selected only the highest level of evidence available to answer each question. Thus, we included clinical studies (Levels I and II-1) or review articles based on Levels I or II-1 evidence. In situations, where the clinical studies were unavailable, uncontrolled studies or expert opinion (Levels II-2 to III) were used.

The CTFPHE system of ranking the quality of evidence applies to assessing causation or the efficacy of an intervention. It does not apply to studies assessing a diagnostic or predictive test, the prognosis of disease, or the economic evaluation of two efficacious interventions. However, quality appraisal criteria for such studies do exist (Leake, 1997) and were employed to classify the recommendations based on other study designs.

7.3 Alternative Forms of PATF

The 1995 report identified three fluoride compounds: 2% sodium fluoride; 8% stannous fluoride; and 1.2% acidulated phosphate fluoride (APF), and three vehicles used to apply these fluorides: brush-on solutions, gels applied in trays, and varnishes. The 1995 report also cited the popularity of APF among dentists and the relative ease of application of gels and recommended the use of APF gel. Since 1992 there has been mounting documentation of the efficacy of fluoride varnishes in preventing caries. This report, therefore, also examines whether fluoride varnish should be recommended over APF.

7.4 Evidence of the Caries Preventive Effects of APF Gels and Fluoride Varnishes

1995 Report

The 1995 report did not identify any clinical study examining or comparing the anti-caries effect of APF gel and fluoride varnish. At the time of that review, experts believed that there was no difference in their effectiveness (Ripa, 1990).

This Review

This review found additional studies on both APF Gel and Varnish and one study with a head-on comparison of the two (Helfenstein and Steiner, 1994a, 1994b; Oliver et al., 1992; Seppa et al., 1995).

7.4.1 Efficacy of APF Gel

In the period examined since the 1995 review, one randomized controlled trial of APF gel has been conducted in two non-fluoridated areas in Quebec (Olivier et al., 1992). As shown in Table 3, biannual application of 1.2% APF gel on children at medium to high risk (3 to 14 defs at the age of 6), showed a statistically significant reduction in caries increments over two years - 0.92 surfaces or 34.3%. However, after stratification by tooth surfaces, only the reduction in occlusal caries remained beyond chance - 0.53 surfaces or 33.8% - over the study period.

This points out an often overlooked finding, namely, that if we use the absolute number of surfaces saved from decay rather than the relative reduction, as the measure of effectiveness, topical fluorides are _more_ effective in preventing pit and fissure caries than they are in preventing smooth surface decay. Thus they can and should be used to prevent new decay in children who are at risk

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for pit and fissure decay.

7.4.2   Efficacy of Fluoride Varnish

We identified one meta-analysis on the caries preventive effect of Duraphat™ fluoride

varnish (Helfenstein and Steiner, 1994a, 1994b). They found eight studies that were of high

quality and provided Level I or Level II evidence. Applying a random effects model on the eight

studies, they estimated that, overall, the use of Duraphat™ results in a 38% reduction (95% CI =

19%-57%) of caries increment.

The random effects model showed that the variation was dominated by the between

studies variation, not by sampling variation. Thus, they reasoned that the inclusion criterion for

all studies to provide standard deviations as well as the mean values was not crucial. An

additional six studies were included in a second analysis, using a specialized statistical procedure

(bootstrap estimate of the standard error). In this analysis, the estimated effect was again a 38%

reduction. However, the 95% CI was much narrower, 25%-50%. These findings provided Level

I evidence of the anti-caries effect of Duraphat™.

7.4.3   Direct Comparison of the Effectiveness of APF Gel and Fluoride Varnish

We identified one head-on comparison of the caries preventive effectiveness of fluoride

varnish and APF gel. Seppa et al. (1995) conducted a 3-year RCT to compare the caries-

preventive effect of NaF varnish and APF gel on high-risk 12-to-13-year-olds. The authors

presented most of the findings graphically. Those available numerically are summarized in Table

4.

Seppa et al. discussed their findings in light of Kingman's "at least as good" criterion for

demonstrating efficacy of a newly introduced product (Kingman, 1992). To claim that fluoride varnish is "as least as good as" APF gel, the upper limit of the 90% confidence interval of the ratio of DMFS increment of the varnish group over that of the gel group has to be less than 110%. For approximal surfaces, the upper limit of the 90% CI was 108% but for all others and for the overall effect the upper limit did not meet the criteria. Thus, APF gel remains the intervention with the higher level of effect.

7.4.4   Harms - Acute Toxicity and Dental Fluorosis: APF Gel Versus Fluoride Varnish

1995 Report

The 1995 report did not discuss the potential harmful effects of PATF. While acute toxicity can occur with excessive ingestion at any age, dental fluorosis is possible only if the excessive ingestion occurs at a time when the tooth enamel is developing, for the central incisors roughly from 20 to from 30 months of age, and later for other teeth (Evans and Stamm, 1991). The effect on the prevalence or severity of fluorosis associated with exposure to two fluoride applications during that period has not been documented.

This Review

Based on the findings of Ekstrand et al. (1980), Mandel (1994) suggested that fluoride ingestion with varnish was lower than that with gel since he felt less fluoride was applied. This review did not identify any recent clinical studies on the harmful effects of PATF. However, three review articles were identified which addressed this issue (Johnston, 1994; Ripa, 1992; Mandel, 1994).

Johnston (1994) reviewed the potential harmful effects of fluoride ingestion from the use of PATF. An application of APF gel (1.2% fluoride) or fluoride varnish (2.3% fluoride) may expose the recipient to as much as 61.5 mg and 11.3 mg of fluoride ions, respectively. It has been shown that, even with suction devices, a considerable amount of fluoride was retained after APF gel-tray treatment (on average 7.7 mg in children, 10.3 mg in adults). Studies on fluoride varnish applications have reported that 0.7 to 14.5 mg. of varnish is used per application. Of this, as much as 75% could be ingested (Johnston, 1995). Thus, Johnston concludes that similar amounts of fluoride are ingested after either gel or varnish treatments. Relating these findings to the established threshold for fluoride nephrotoxicity, 50 µmol/l, and to the 'probably toxic dose', 5 mg/kg of body weight, he found that topical fluorides gave cause for concern.

Johnston (1994) also cited two clinical studies on the long-term effect of fluoride ingestion from PATF in his review. One retrospective study identified fluoride gel applications as a risk factor for fluorosis among children in an optimally fluoridated area. The second, more powerful, study found no increased prevalence of dental fluorosis in children aged 14-16, after as many as five annual gel applications since the age of 6 to 7.

In his review on fluoride gel-tray treatments, Ripa (1992) also discussed the significance of fluoride retention after gel treatments. In particular, the author stated that dental fluorosis was evidence of systemic fluoride intake that was too high. Furthermore, he suggested that the ingestion of 10 or more mg of fluoride would exacerbate this overexposure.

8.0   Comparison of Relative Outcomes and Costs of APF Gel and Varnish

Table 5 compares APF gel and fluoride varnish according to five criteria:

- Devices and clinical procedure;

- Ease of use in clinical setting;

- Cost of implementation;

- Cost per patient;

- Quality of evidence supporting their use.

As evident from Table 5, the cost difference between operating a caries prevention

program with APF gel or fluoride varnish may be substantial when the application time estimates

are considered. Our own estimates of clinical time for the APF gel (inclusive of admission,

treatment, discharge and clean –up) is 20 minutes. This contrasts with Seppa's estimate for

application of 6 minutes for the gel and 2 minutes for the varnish. If the ratio of times held, then

a varnish application would take about seven minutes in the NYPHD clinics, a considerable

saving. However Seppa's time estimates are not well supported and further research needs to be

done. Accordingly, based on the well-supported effects and costs APF gel will remain the

intervention of choice.

9.0   APF gel application protocol

While APF gel is the choice for the application of PATF, it is evident that it would not be

cost-effective to apply PATF to all children, especially to those who are not likely to experience

new decay. Thus, to ensure that the outcomes are maximal for the resources committed, we

studied the following questions:

- who can benefit from PATF?

- how often should PATF be provided?

- is cleaning required prior to PATF?

- should cleaning be followed by PATF?

- how much of the fluoride preparation should be used? and

- for how long should the fluoride preparation be retained in the mouth?

9.1 Who Can Benefit from APF Gel?

1995 Report

The 1995 report made reference to three clinical studies which investigated the combined effect of a PATF, pit and fissure sealants and water fluoridation (Szwejda, 1972; Bagramian, 1982; Bohannan et al., 1985). The findings suggested that, for annual applications to those living in an optimally fluoridated community and receiving pit and fissure sealants, the incremental anti-caries protection from PATF treatments was minimal. Therefore, PATF does not make a sufficiently large difference in reducing caries for the average low to moderate caries-risk child living in a fluoridated community.

The 1995 report did not examine clinical studies that evaluated risk markers for caries in children. Instead the authors analyzed 1990 North York data and summarized expert opinion. Past caries experience and pattern were cited predictors of caries risk and pattern. They suggested that children with pit and fissure caries would benefit more from occlusal sealants than PATF. The 1995 review concluded that:

"Children who have experienced limited pit and fissure decay were not necessarily at high risk for smooth surface caries, and should not receive topical fluoride. Use of topical fluoride should be directed toward children with one or more decayed smooth surfaces." Based on this conclusion, the 1995 report recommended that "Children with one or more decayed smooth surfaces should receive PATF."

This Review

We did not identify any recent studies that would allow us to estimate the effectiveness of PATF in fluoridated areas such as North York. Therefore, two studies on stannous fluoride solution, conducted in fluoridated communities in the 1960s, have been included here to supplement the evidence provided in the 1995 review.

Horowitz and Heifetz (1969) studied the effectiveness of stannous fluoride in a fluoridated community in Tennessee. When applied for four minutes annually, 8% stannous fluoride solution was found to bring about statistically significant reduction of DMFT and DMFS after three years, 21.5% (95% CI = 6.3-36.7) and 20.7% (95% CI = 3.4-38.0), respectively.

Muhler (1960) also demonstrated the effectiveness of stannous fluoride solution in a fluoridated community. He found that biannual applications of an 8% solution resulted in statistically significant reduction in DMFT and DMFS after 30 months, 54% (p=0.002) and 49% (p=0.004), respectively.

As would be expected, the prevalence and extent of caries among subjects in these earlier studies samples were higher than currently experienced in North York. The baseline DMFT and DMFS for Horowitz and Heifetz's group of grade 2, 3 and 4 students, with a mean age of 8.1

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years, were 0.75 and 1.09, respectively. Muhler's group, aged 6 to 14 years, had an initial DMFS ranging from 1.1 for 6-year-olds to 14.4 for 13-year-olds. Corresponding surface scores for the population in North York are not available for direct comparison. However, North York 9-year-olds had an average DMFT 0.63 and 13-year-olds had a DMFT 1.56 in 1994 (OMH Dental Index System). Therefore, while the two studies demonstrated the effectiveness of topical fluoride in fluoridated areas, the size of the effect may not be as large among North York children who have lower caries scores.

This review did not find any controlled studies that identified the patient groups that would benefit most from PATF. The findings from Olivier et al. (1992) study, - see Table 3 show that PATF brought about a significant anti-caries effect in the moderate to high-risk group, i.e., those with an initial mean defs of 3 to 14. The anti-caries effect was lost in the extremely high-risk group (baseline defs of 15 and over) suggesting that, for extremely high-risk children, PATF is insufficient to produce noticeable caries reduction.

Nonetheless, to ensure the appropriate use of PATF, namely that the benefits outweigh the potential risks and provide value for the resource costs incurred compared to alternate uses of those same resources, children at higher risk of caries have to be identified.

9.2 Identifying High-risk Children

A number of risk markers have been suggested (Songpaisan et al., 1995; Johnston, 1994; Ripa, 1992; Lewis et al., 1995) including:

i.   Demographic and socio-economic factors:

- age

- poverty

ii. Environmental factors:

- non-fluoridated community

iii. Caries history/activities

- high defs/DMFS count

- development of new caries lesions on previously sound tooth

- secondary lesions associated with restoration margins

iv. Conditions that increase the risk for caries

- ongoing orthodontic treatment

- compromised salivary flow as a result of radiation therapy, chronic medication and medical conditions

- high counts of micro-organisms

The importance of past caries experience as a risk marker was shown in two observational studies. In a 3-year study, Mattiasson-Robertson and Twetman (1993) found that salivary mutans streptococci score and past caries, defined as number of colony forming units on per $cm^2 \geq 30$ and DMFS > 4, respectively, were predictive of caries risk. Holt (1995) demonstrated that those who were caries-free at baseline developed fewer lesions during the follow-up period. On the other hand, he found that 9-year-olds with a baseline dmfs of 1 to 5 had the same caries increment as those with a baseline dmfs of 6 and above. These findings are parallel to observation made on 1990 North York data which suggested that children with a DMF of 1 or more had a higher probability (42%) of having one or more newly decayed teeth than

children with a DMF of 0 (24%) (Woodward and Lewis, 1995).

The superiority of past caries experience as a predictor of caries risk was also demonstrated in a discussion paper, unpublished, by Hausen (1996). The power of six predictors - baseline DMFS; mutans streptococci score; salivary flow rate; sucrose intake frequency score; brushing frequency score and social group - were compared using ROC-curves from a cohort of 350 13-year-olds. The predictive power of baseline DMFS score was clearly the highest. In fact, baseline DMFS was the only measure which predicted better than random guessing; its ROC-curve was the only one that differed visually from the no information line.

According to conventional practice and as shown above, PATF is an appropriate anti-caries measure for children at medium to high risk for both smooth surface and pit and fissure caries and past caries has been shown to be a reliable risk marker for overall risk for caries.

For children at risk for pit and fissure caries, sealants would be the treatment of choice given their higher rates of effectiveness over the longer term. However, there are instances where the procedure, though indicated, cannot be performed. In North York, parent refusal - lack of compliance from the patient - and partially erupted teeth - may preclude pit and fissure sealant as a preventive measure. Since there is Level I evidence to support that PATF is effective against pit and fissure caries (Olivier, 1992), PATF may be recommended.

Recommendation

Children with one or more decayed surfaces and especially those whose permanent molars should, but cannot be sealed, should receive the PATF (Level of Evidence: I; Classification of recommendation: B).

9.3   How Often Should APF Gel Be Applied?

<u>1995 Report</u>

The 1995 report identified one completed clinical study that compare the anti-caries effect of annual and biannual applications of PATF, APF solution (Horowitz and Doyle, 1971). It also included the interim results of a 3-year study conducted by Lewis (1992). The findings suggested that there was no greater anti-caries effect when topical fluoride was applied biannually instead of annually. The authors of the 1995 review concluded that:

"No scientific evidence exists to support the belief that biannual applications of topical APF gel result in greater caries reduction than annual applications."

Based on this conclusion, the authors recommended that:

"Children with one or more decayed smooth surfaces should receive the annual

topical fluoride treatments on the year of diagnosis and the following year."

<u>This Review</u>

For this review, the published results of the 3-year randomized community-based clinical trial (Johnston and Lewis, 1995) were available. The study compared the anti-caries effect of APF gel - annual versus biannual applications, and prior cleaning versus no prior cleaning. The four treatment groups are shown in Table 6 and the results in Table 7.

Even though the results of this study showed no statistically significant difference in caries increments between annual and biannual APF gel applications, it is worth noting that across all 4 groups there was a trend for biannual applications to produce greater caries reduction

than annual applications: a 1.6% to 22% difference.

Thus, two randomised trials have found no difference between the two frequencies of application. However, as was pointed out in our review process, the studies could not control for the number of additional PATF received from private dentists. Thus, if a child were receiving the traditional two applications per year from the family dentist, the studies were really testing the difference in effect between three and four applications per year and little or no difference would be expected. While one might expect that most parents would not pay the family dentist for fluoride applications when the child was receiving them as part of the trial, we cannot rule out that this occurred. Thus, the external review committee felt there was insufficient evidence to recommended only one application per year, and recommend that the traditional twice yearly applications be re-instituted.

Conclusion

Two studies have shown that biannual APF gel applications are no more effective than annual applications of APF gel (Level of evidence: I). However, it is not clear that the study subjects did not receive additional APF applications outside the study and, therefore, there is insufficient evidence that once a year is effective.

Recommendation

In contrast to the 1995 report, APF gel should be provided on a biannual basis (Level of Evidence: I; Classification of recommendation: A).

9.4   Is Cleaning Required Prior to APF Gel Applications?

<u>1995 Report</u>

The 1995 report identified three randomised clinical studies that investigated the need for a cleaning prior to PATF. All three found that there was no difference in the anti-caries effect of PATF with and without prior cleaning. It was therefore concluded that:

"A prophylaxis is not necessary before a topical fluoride application."

Based on this conclusion, it was recommended that:

"No prophylaxis is necessary before the application of topical fluoride."

<u>This Review</u>

Johnston and Lewis' study (1995) discussed above also examined the anti-caries effect of APF gel with and without prior cleaning. The comparison of the dmfs/DMFS or DMFS increments across the 4 groups, 6-7 year-olds and 10-11 year-olds, and annual and biannual applications, showed no apparent advantage or disadvantage of a cleaning before gel applications (see Table 7). While additional cleanings might also have been provided outside the study, in this case the finding is supported by the previous randomised trials where cleaning was tested directly.

<u>Recommendation</u>

As per 1995 report, for dental caries prevention, cleaning is unnecessary before the application of topical fluoride (Level of evidence: I; Classification of recommendation: E).

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9.5 Should Cleaning be Followed by the APF Gel Applications?

1995 Report

The authors noted that the clinical significance of a post-cleaning risk of decay has never been studied directly. Therefore, the results from two studies which investigated the cariostatic effect of fluoridated versus non-fluoridated prophylaxis pastes were examined to determine indirectly the impact of a cleaning without a subsequent PATF on a child's susceptibility to tooth decay (Axelsson and Lindhe, 1974; Lindhe et al., 1975; Axelsson and Lindhe, 1975). A fluoridated prophylaxis paste was no more effective in caries prevention than a non-fluoridated paste. Ripa et al. (1976) conducted a two-year study and showed that biannual cleaning had no cariostatic effect. Despite the lack of evidence to suggest that a single cleaning increases a child's risk of caries, fluoridated prophylaxis pastes are recommended over non-fluoridated pastes when the procedure is not be followed by PATF (American Academy of Paediatric Dentistry, 1992; Johnston, 1992). The 1995 report concluded that:

> "Prophylaxis and topical fluoride use should be considered independently of one another. There is no evidence to suggest that an annual or biannual prophylaxis alone, without a subsequent application of topical fluoride, will increase a child's risk of caries. Therefore, a topical fluoride treatment is not necessary following a prophylaxis."

Hence, it was recommended that:

> "It is not necessary to follow a prophylaxis with a topical fluoride application unless a topical is indicated based on the child's oral health status. If no topical fluoride treatment will follow a prophylaxis, a fluoridated prophylaxis paste is

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recommended."

This Review

It is acknowledged that rubber-cup prophylaxis (cleaning) is required to remove extrinsic stain from teeth. This review did not identify any additional published studies that examined the need to follow a cleaning with PATF. However, Johnston (1994) suggested that fluoridated prophylactic paste might be used when no topical fluoride application was to follow the cleaning procedure.

As per 1995 report: professional cleaning and topical fluoride use should be considered independently of one another. There is good evidence to suggest that an annual or biannual cleaning alone, without a subsequent application of topical fluoride, will not increase a child's risk of caries (Ripa et al., 1976). Therefore, a topical fluoride treatment is not necessary following a cleaning (Level of evidence: I)

Recommendations

As per 1995 report, rubber-cup prophylaxis (cleaning) is required to remove extrinsic stain from teeth. It is not necessary to follow a cleaning with a topical fluoride application unless a topical is indicated based on the child's oral health status (Ripa et al., 1976), (Level of evidence: I; Classification of recommendation: E). If no topical fluoride treatment will follow a cleaning, a fluoridated prophylaxis paste is recommended (AAPD, 1992), (Level of evidence: III; Classification of recommendation: C).

9.6 How Much of the APF Gel Should be Used? and

9.7 What General Procedure Should be Followed?

1995 Report

The 1995 report did not include any clinical studies that examine the impact of the amount of gel used on the plasma fluoride concentration and on the anti-caries effect. However, based on the recommendations on the use of PATF from four review articles (Lecompte, 1987; Johnston, 1992; Ripa, 1987, 1991), the following conclusion and recommendation were drawn. "To reduce fluoride ingestion only enough gel should be applied to cover all teeth, but this should not exceed 2-2.5 grams of gel per tray or over 40% of the tray's volume. Patients should be seated upright, suction should be used during and after the application, and expectoration should occur for at least 30 seconds immediately following the procedure. For young children, the fluoride gel should be wiped off after application."

"APF gel should be used and applied using a styrofoam tray. Enough gel should be used to completely cover the teeth, but this should be no more than 2-2.5 grams per tray or 40% of the tray's volume... Patient should expectorate for at least 30 seconds after the fluoride trays are removed, and gel should be wiped from teeth of young patients. All patients should be instructed on to eat or drink anything for at least 30 minutes."

This Review

This review did not reveal any new clinical trials on this research question. However, the issue had been reviewed again by a number of authors (Johnston, 1994; Ripa, 1992; Lewis et al., 1995). There was consensus on the need to minimize the amount of fluoride ions ingested while

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maximizing fluoride absorption by enamel. The following steps have been recommended by these authors:

1. Minimize ingestion of fluoride:

    - sit patient upright;

    - use a maximum of 2.5-4 ml per full size trays (less for small trays);

    - use tray with absorptive liners;

    - use high-speed suction during and after the procedure; and

    - ask patient to expectorate for a minute after tray is removed.

2. Maximize absorption of fluoride by enamel:

    - select tray that cover all sites;

    - dry each arch then insert upper tray and lower tray separately;

    - apply saliva absorbers to the parotid duct openings for difficult cases; and

    - ask patient not to rinse, eat or drink for 30 minutes after the procedure.

Most of these recommendations have been put forward in the 1995 review. Those not included have been incorporated into current recommendations as deemed appropriate.

Conclusion

To minimize fluoride ingestion only enough gel should be applied to cover all teeth, and this should not exceed 2-2.5 grams of gel per tray or over 40% of the tray's volume. Patients should be seated upright, high-speed suction should be used during and after the application, and expectoration should occur for at least 30 seconds immediately following the procedure. For young children, the fluoride gel should be wiped off after application. To maximize fluoride

uptake the selected tray should cover all teeth which should be air dried before gel application. Patients should be instructed not to eat or drink for 30 minutes after the procedure (Johnston, 1994; Ripa, 1992; Lewis et al., 1995) (Level of evidence: III).

Recommendation

Enough gel should be used to completely cover the teeth, but this should be no more than 2-2.5 grams per tray or 40% of the tray's volume. Teeth should be air-dried before gel application. Patient should be seated upright and suction should be used during the procedure. After the procedure, patient should be instructed to expectorate for at least 30 seconds, and gel should be wiped from teeth of young patients. All patients should be instructed not to eat or drink anything for at least 30 minutes (Level of evidence: III, Classification of recommendation: C).

9.8   For How Long Should the APF Gel be Retained in the Mouth?
1995 Report

The authors could not locate any clinical trials comparing the cariostatic effectiveness of 1-minute versus 4-minute application of APF gel. Fluoride uptake was shown to be significantly greater after 4 minutes than one minute by one in vitro and one in vivo experiment (Wei and Hattab, 1988; Wei et al., 1988). These findings supported expert recommendations on the adoption of a 4-minute application time. Based on these findings, the following conclusion and recommendation were made.

"Topical fluoride application time should be 4 minutes, not 1 minute."

"... Gel should be retained on the teeth for 4 minutes ..."

This Review

This review did not identify any clinical study on the relationship between exposure time and effectiveness of PATF. Two in vitro experiments have been completed but they yielded conflicting findings. Garcia-Godoy et al. (1995) found that lesions artificially created after a 1-minute versus a 4-minute APF gel exposure were no significantly different in size. Using 2% NaF solutions at pH 3.5 and 5.5, Cruz and Rolla (1992) showed that the amount of calcium fluoride deposit increased rapidly with time of exposure. The validity of these findings is questionable due to the limited power of the two studies. The sample-size of both studies was small with 10 or fewer subjects in each treatment group. The statistical tests used were not appropriate for the study design, further undermining the findings. A number of review articles have been published (Johnston, 1994; Ripa, 1992; Wei and Yiu, 1993). There is consensus among authors on the use of a four-minute exposure to optimize the benefit of APF gel. Hence, the recommendation of the 1995 report was upheld.

Recommendation

As per 1995 report, topical fluoride application time should be 4 minutes, not 1 minute (Johnston, 1994; Ripa, 1992; Wei and Yiu, 1993), (Level of evidence: III; Classification of recommendation: C).

10.0   Summary of Evidence-based recommendations and any minority views

APF Gel and Fluoride Varnish

Both APF gel (Olivier et al., 1992) and fluoride varnish (Helfenstein and Steiner, 1994a 1994b) are efficacious and can be recommended (Level of Evidence: I; Classification of recommendation: A).

Fluoride varnish while efficacious, has not been found to be superior to or "at least as good as" APF gel (Seppa et al., 1995). However, there may be a significant cost advantage in favour of the varnish but it is poorly documented. Thus, APF gel remains the first choice of PATF (Level of Evidence: I; Classification of recommendation: B)

Application Procedure of APF Gel

This review identified scientific evidence which supports the recommendations made in the 1995 report regarding the application procedure of APF gel. Based on additional evidence, the recommendations made in relation to the questions: who should receive APF gel application and what general procedure should be followed, have been expanded. All recommendations are listed below:

Who should receive PATF?

- Children with one or more decayed surfaces and especially those whose permanent molars should, but cannot be sealed should receive PATF (Level of Evidence: I; Classification of recommendation: B).

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How often should PATF be provided?

- APF gel should be provided on a biannual basis (Level of Evidence: I; Classification of recommendation: A).

Is cleaning required prior to PATF?

- No cleaning is necessary before the application of topical fluoride (Level of Evidence: I; Classification of recommendation: E).

Should cleaning be followed by PATF?

- It is not necessary to follow a cleaning with a PATF unless a topical fluoride is indicated based on the child's oral health status (Level of Evidence: I; Classification of recommendation: E). If no topical fluoride treatment will follow a cleaning, fluoridated prophylaxis paste is recommended for the cleaning (Level of Evidence: III; Classification of recommendation: C).

How much of the fluoride preparation should be used and what general procedure should be followed?

- Enough gel should be used to completely cover the teeth, but this should be no more than 2-2.5 grams per tray or 40% of the tray's volume. Teeth should be air-dried before gel application. The patient should be seated upright and suction should be used during the procedure. After the procedure, the patient should be instructed to expectorate for at least 30 seconds, and gel should be wiped from teeth of young

patients. All patients should be instructed not to eat or drink anything for at least 30 minutes (Level of Evidence: III; Classification of recommendation: C).

For how long should the fluoride preparation be retained in the month?

- APF gel should be retained in the mouth for 4 minutes (Level of Evidence: III; Classification of recommendation: C).

11.0   Comments and Further Research

While for now APF gel is the preferred form of PATF, studies lacked the power to demonstrate clinical equivalence or superiority. Further studies are needed to compare the amounts used per patient, the relative costs and patient acceptablility of the application of varnishes.

12.0 Tables

Table 1. Tooth Surfaces Attacked per Thousand Surfaces at Risk in Permanent Teeth by Type of
Surface in US Children in 1980 and 1987

Type of surfaces	1980	1987	Difference	Percent Reduction
Pit & fissure of molars & premolars (including buccal pits & lingual grooves)	191.46 (84%)	135.93 (89%)	55.53	31.03
Approximal surfaces of molars & premolars	27.31 (12%)	13.40 (9%)	13.90	51.86
All other surfaces	8.21 (4%)	3.71 (2%)	4.50	59.10

Source: Li et al., 1993

Table 2. Mean DMFS by Fluoride History and Tooth Surface

Fluoridation	Total	Occlusal pit/fissure	Buccal/Lingual pit/fissure
Lifelong history	1.66	0.75 (45%)	0.53 (32%)
No history	2.52	1.13 (45%)	0.74 (29%)

Source: Clark et al., 1995

Table 3. Two-year mean DMFS increments for Quebec test and control groups

Stratum (Baseline defs)	Incidence of Caries									
	Test Group				Control Group				Difference	
	Total	Occ.	B-L	M-D	Total	Occ.	B-L	M-D	Abs.	%
All	2.94				3.24				0.30	9.3
3 to 14	1.76				2.68				0.92[*]	34.3
		1.04				1.57			0.53[*]	33.8
			0.63				0.99		0.36	36.4
				0.09				0.12	0.03	25.0
≥15	3.45				3.52				0.07	2.0

Source: Olivier et al. 1992

Note: Occ. = occlusal surfaces; B-L = bucco-lingual surfaces; M-D = proximal surfaces
Abs. = Absolute difference; % = Percent difference

[*]p-value ≤ 0.05

Table 4. DMFS increments for the APF Gel and Fluoride Varnish Subjects

Surfaces	Ratio (DMFS increment for varnish / DMFS increment for gel	Difference (DMFS increment for gel - DMFS increment for varnish)	
		Absolute	Percentage
All	0.88	0.45	12%
Occlusal	1.07	---	-7%
Bucco-lingual	0.85	---	15%
Approximal	0.76	---	24%

Source: Seppa et al., 1995

Table 5. Comparison of costs of providing APF Gel and Fluoride Varnish

	APF Gel	Fluoride varnish
Device & clinical procedure	Acidulated phosphate fluoride (1.23% fluoride); applied using styrofoam trays	Sodium fluoride (2.26% fluoride); applied using a small brush or cotton swab
Ease of use	Easy	Easy
Costs: Implementation Material Application (time)	Negligible Minimal 2 X 20 minutes annually* 2 X 6minutes annually**	Negligible Minimal 2 X 2 minutes annually**
Quality of Evidence	Level I, Class A	Level I, Class A

* Source: Woodward et al., 1994
** Source: Seppa et al 1995

Table 6. Treatment of the Four Test Groups

Prior Cleaning	Application Frequency	
	Annual	Biannual
No	- annual fluoride gel tray application	- biannual fluoride gel tray application
Yes	- rubber cup cleaning using a non-fluoride prophylaxis paste - annual fluoride gel tray application	- rubber cup cleaning using a non-fluoride prophylaxis paste - biannual fluoride gel tray application

Source: Johnston and Lewis, 1995

Note: All fluoride applications were provided by one of two hygienists or one preventive dental assistant using the manufacturer's recommended methods.

Table 7. Caries increments by frequency of application (dmfs/DMFS for 6-7 year-olds and DMFS for 10-11 year-olds)

	Frequency of application		Difference (annual - biannual)	
	Annual	Biannual	Absolute	Percentage (%)
6-7 year-olds without cleaning	3.82	3.53	0.29	7.6
6-7 year-olds with cleaning	5.04	3.93	1.11	22.0
10-11 year-olds without cleaning	2.54	2.50	0.04	1.6
10-11 year-olds with cleaning	2.46	2.22	0.24	9.8

Source: Johnston and Lewis, 1995

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