A comparison of the costs and patient acceptability of professionally applied topical fluoride foam and varnish


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of professionally applied topical fluoride (PATF) in two alternative forms, foam or varnish. Fluoride foam was applied in trays while fluoride varnish was painted on tooth surfaces.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised schoolchildren with a high risk for dental caries, as determined by the presence of at least one smooth surface carious lesion.

Setting
The setting of the study was primary care. The economic study was conducted in Canada.

Dates to which data relate
The dates to which the effectiveness and cost data referred were not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was conducted alongside the effectiveness study and was undertaken on the same patient sample.

Study sample
A sample size of 160 (16 per group for each of the 5 dental hygienists initially participating in the study) was required to detect differences in procedural time between the two assessed methods. This estimate was calculated using a standard formula with an alpha of 0.05, a beta of 0.15, and a minimum detectable difference of 1 minute. After the analysis of data from 164 cases, it was determined that at least 250 cases were required to assess differences in other categorical measures. The study was then expanded to include 3 more dental hygienists.

The study sample consisted of a convenience sample of schoolchildren from the York region and the City of Hamilton, ON, Canada. A school-based dental screening programme identified these children as requiring PATF. No evidence
was provided that the initial study sample was appropriate for the clinical study question. A total of 256 children, aged 3 to 15 years (mean age 8.0), participated in the study. Children with asthma were only given foam because of the risk of adverse reactions with varnish application. The number of children allocated to each group was not reported. One child refused any fluoride treatment and, therefore, might have been excluded from the analysis, although this was not explicitly stated.

**Study design**

The study was a non-randomised controlled trial. The children were assigned to groups according to the time of day they were scheduled to have fluoride treatment. Fluoride foam was applied for morning appointments and varnish was applied during afternoon appointments. The study was conducted in Canada. Eight public dental hygienists (5 in the York region and 3 in Hamilton) applied the selected PATFs. An observer recorded the time of procedure and adverse outcomes during the procedure. Patient acceptability was measured shortly afterwards. At the completion of the study, the views of the participating dental hygienists on the methods assessed were also obtained. No loss to follow-up was reported.

**Analysis of effectiveness**

It was not stated whether all the patients initially included in the study were accounted for in the analysis. The outcomes measured were the time to perform each procedure, adverse outcomes during the fluoride application, patient satisfaction and hygienist acceptability of the procedure. The effectiveness of caries prevention and the amount of fluoride ingested during the procedure were not measured. The adverse outcomes examined included vomiting, crying, gagging, excessive arm or leg movements, and other signs of distress.

After each fluoride application, the observer questioned the children about their satisfaction with the procedure. The questionnaire, consisting of multiple-choice questions, was not validated and was based on a published relevant questionnaire. At the completion of the study, to hygienists were given a self-administered questionnaire on their views of the PATFs used during the study.

No evidence was provided that the groups were comparable at baseline. It was also not stated whether any adjustments for confounding factors were made.

**Effectiveness results**

The mean time of the procedure was 5.81 minutes (standard deviation, SD=1.62) for varnish application and 7.86 minutes (SD=1.63) for foam application, (p<0.0001).

The percentage of children who showed signs of gagging during the procedure was 3.8% in the varnish group and 15.1% in the foam group, (p=0.002).

The percentage of children who cried during the procedure was 1.5% in the varnish group and 3.2% in the foam group, (non significant difference).

The percentage of children who showed other signs of distress (e.g. excessive fidgeting) was 2.3% in the varnish group and 9.5% in the foam group, (p=0.014).

A significantly higher percentage of children in the foam group stated that they would be unhappy if they had to have fluoride again the next day (19.8% versus 7.1%, p=0.03), and that the fluoride application made them feel as if they wanted to gag, (31.7% versus 16.0%, p=0.02).

No significant differences were found between the two groups in the percentage of children that felt nervous during the treatment, or found the treatment unpleasant.

These results were also analysed by age and were, in general, more favourable for varnish applications in children aged 3 to 6 years.
All hygienists rated varnish as good or better than foam in terms of procedural time and their ability to control the patient's ingestion of fluoride.

The results for other questions tended to favour the use of varnish. No hygienist rated varnish as much worse than foam.

**Clinical conclusions**
Varnish applications were found to take less time. They resulted in fewer signs of discomfort and greater patient acceptability.

**Measure of benefits used in the economic analysis**
The clinical outcomes were left disaggregated and no summary measure of benefit was used in the economic analysis. In effect, a cost-consequences analysis was performed.

**Direct costs**
The costs of the health service were included. These were for labour, fluoride (in the form of foam or varnish) and supplies specific for the method used (styrofoam trays for foam application, brush tips and cotton rolls for varnish application). The costs of supplies used in both techniques (e.g. saliva ejectors) were not included in the estimation of the costs. The costs were reported as the cost per application, with unit costs being reported separately. The costs were estimated using actual data derived from the trial. The labour costs were based on data supplied by the York Region Health Services Department and the City of Hamilton Social and Public Health Services. Discounting was not carried out as the costs were incurred within one day. The date to which the quantities and prices referred was not reported.

**Statistical analysis of costs**
The costs were treated deterministically. No analysis of the costs was undertaken, but treatment time was evaluated statistically.

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
Canadian dollars (Can$).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total cost per application was $3.69 for varnish and $4.11 for foam.

Varnish application was $0.42 less expensive than foam.

The costs of treating dental caries, potentially resulting from the failure of PATF preventive action, were not included in the estimation of the total costs.
Synthesis of costs and benefits
Not applicable as the study was, in effect, a cost-consequences analysis.

Authors' conclusions
Fluoride varnish applications were found to take less time and resulted in fewer signs of discomfort and higher patient acceptability. They could also be provided at a lower cost than foam applications.

CRD COMMENTARY - Selection of comparators
The selection of the comparator was implicitly justified, as foam represented one of the two widely used methods of PATF in Canada. It would have been informative had gel also been evaluated. You should decide whether this technique represents routine practice in your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis was a non-randomised controlled trial. The design might have been associated with bias at the stage when the children were assigned to groups, owing to the lack of randomisation. For example, it is possible that older children with heavier school programmes were booked for afternoon (varnish) treatment, resulting in the varnish group consisting of significantly older children than the foam group. This may have introduced bias into the analysis, as the age of the participants was shown to be correlated with study outcomes. Children with asthma were not given varnish because of the risk of adverse reactions, and were assigned directly to the foam group. This introduced additional bias in the analysis, as the foam group included children with a generally higher risk for adverse events, which was one of the outcomes assessed. Children with asthma should, ideally, have been excluded from the study in order to avoid bias.

The study sample was a convenience sample and might not be representative of the study population. However, the authors felt that this would not be the case because the children were selected over several months and health clinics treated patients from different areas of each region. There was no evidence that the patient groups were comparable at analysis. No statistical analyses were undertaken to take potential biases or confounding factors into consideration.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The study was, in effect, a cost-consequences analysis.

Validity of estimate of costs
The perspective of the study was not stated, but it seems to have been that of the health service. As such, all the categories of cost relevant to this perspective were included in the analysis. Some relevant costs common to both PATF methods, such as the costs of supplies used in both techniques, were excluded from the analysis, but this is unlikely to have affected the authors’ conclusions. The unit costs were reported for each cost element included in the analysis, which improves the generalisability of the results. No statistical analysis of the costs was conducted. Therefore, the significance of cost-differences between the two PATF methods could not be established. Since the costs were incurred within one day, discounting was unnecessary and was not carried out. The date to which the quantities and prices referred was not reported, which limits the reproducibility of the results.

Other issues
The authors reported findings of other studies, which were consistent with their own findings. The issue of the generalisability of the results was not addressed. A number of further limitations of the study were reported. For example, the fact that the participants and observers were not blinded to the PATF technique used. In addition, two factors might have favoured the results of the foam group. First, the participating hygienists’ experience of using varnish for caries prevention may have been limited. Second, the initial resistance to the use of varnish reported by some hygienists. However, the impact of these limitations on the results was considered minimal. The results were adequately reported. The authors’ conclusions reflect the scope of the analysis.
Implications of the study
The authors suggested that, in public dental programmes that have a large volume of patients, the use of PATF in the form of varnish might result in substantial savings in money or hygienist time. Varnish has also been reported to have other advantages over gel or foam in its application, and was equally effective for caries prevention. Therefore, the authors recommended the use of fluoride varnish when treating children at high risk for caries in public health settings.

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