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Cost-Effectiveness through the Dental-Health FRAMM Guideline for Caries Prevention among 12- to 15-Year-Olds in Sweden

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Keywords

Adolescents · Approximal caries · Caries prevalence · Community dental health · Cost-effectiveness · Fluoride varnish · Guideline · School-based guideline

Abstract

Since 2008, FRAMM has been a guideline for caries prevention for all 3- to 15-year-olds in the Västra Götaland Region in Sweden and a predominant part is school-based fluoride varnish applications for all 12- to 15-year-olds. The aims were to evaluate dental health-economic data among 12- to 15-year-olds, based on the approximal caries prevalence at the age of 12, and to evaluate cost-effectiveness. Caries data for 13,490 adolescents born in 1993 who did not take part and 11,321 adolescents born in 1998 who followed this guideline were extracted from dental records. Those with no dentin and/or enamel caries lesions and/or fillings on the approximal surfaces were pooled into the "low" subgroup, those with 1–3 into the "moderate" subgroup and those with ≥4 into the "high" subgroup. The results revealed that the low subgroup had a low approximal caries increment compared with the moderate and high subgroups during the 4-year study period. In all groups, there were statistically significant differences between those who took part in the guideline and those who did not. The analysis of cost-effectiveness revealed the lowest incremental cost-effectiveness ratio (ICER) for the high subgroup for decayed and/or filled approximal surfaces (DFSa) and approximal enamel lesions together and the highest ICER for the low subgroup for DFSa alone. To conclude, the FRAMM Guideline reduced the caries increment for adolescents with low, moderate and high approximal caries prevalence. The subgroup with the most favourable cost-effectiveness comprised those with a high caries prevalence at the age of 12.

Introduction

Although the prevalence of caries has decreased among children and adolescents during the last 40 years in high-income countries, dental caries still remains a common disease worldwide, generating high costs for individuals and society. There is broad consensus that fluoride prevents caries at all ages [Griffin et al., 2007; Marinho et al.,

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2009], and many reviews and meta-analyses support fluoride varnish for caries prevention in both the primary and the permanent dentition [Seppä, 1991; Helfenstein and Steiner, 1994; Petersson et al., 2004; Azarpazhooh and Main, 2008; Carvalho et al., 2010; Weyant et al., 2013]. The results of the latest Cochrane Review by Marinho et al. [2013] were in accordance with those in an earlier review [Marinho et al., 2002] and showed that twice-yearly applications of fluoride varnish reduce DMFS increments by 43% (95% CI 30–57%) for children and adolescents. One important issue today is the implementation of evidence-based research in clinical practice and an attempt to identify the best value for money. From a public-health perspective, limited resources should be used in the most effective way to obtain the largest health care gain.

In 2008, a guideline called FRAMM was implemented for all 3- to 15-year-olds in the Västra Götaland Region, with 1.6 million inhabitants, in Sweden. Fluoride varnish applications twice a year at 6-monthly intervals for all 12- to 15-year-olds is one important part of this guideline, together with lessons on oral health, based on the good results of a randomised controlled trial from this region [Moberg Sköld et al., 2005; Sköld et al., 2008]. A low caries increment at a low cost at population level was shown by Bergström et al. [2016a] for all 12- to 15-year-olds in the Västra Götaland Region, according to this guideline.

The aims were to evaluate dental health-economic data among 12- to 15-year-olds, based on the approximal caries prevalence at the age of 12, and to evaluate the cost-effectiveness of this FRAMM Guideline. Our hypotheses were that the approximal caries increment was influenced by the approximal caries prevalence at baseline, further, that the caries increment was higher without this guideline and, finally, that the guidelines can be assumed to be cost-effective.

Materials and Methods

The Regional Dental-Health FRAMM Guideline in the Västra Götaland Region

The regional dental-health guideline is called FRAMM which is an acronym of the most important parts of this guideline, namely "fluoride," "advice," "arena," "motivation" and "diet" (in Swedish, the words *fluor*, *råd*, *arena*, *motivation* and *mat*). This guideline was implemented on a broad scale in the Västra Götaland Region in 2008, and, as a result, the 112 public dental clinics have clearly written instructions for population-based caries prevention for all children and adolescents up to the age of 15.

The population-based guideline for the 12- to 15-year-olds has the school as a dental health arena. Important aspects include brief information about oral health together with supervised dental flossing and approximal applications of fluoride varnish (Duraphat®, 2.26% F) every 6 months, performed by dental nurses. During this period, the dental nurses also include two lessons about oral health and tobacco use.

The adolescents from 11 of the 112 public dental clinics have an extended high-risk intervention, as they come from geographical areas with a lower socio-economic status and therefore run a higher risk of caries. FRAMM for these areas starts when the children are just 6 years of age, and the number of fluoride varnish applications at school is 4 times a year every 3 months.

One of the main goals for the FRAMM Guideline is to promote good daily home care, such as toothbrushing twice a day with fluoridated toothpaste, and to establish and maintain good dietary habits. The most common dental personnel implementing the guideline are dental nurses.

The population-based intervention and the high-risk intervention in FRAMM, as well as regular dental check-ups at the public dental clinics, are free of charge for all adolescents, as Sweden has a system with tax-subsidised dental care for all children and adolescents, normally up to the age of 20. The majority of all adolescents visit the public dental clinics at an interval of 18 months, when the risk of caries is considered to be low or medium. At these check-ups, the adolescents receive one fluoride varnish application on a routine basis. The small number of high-risk adolescents, approximately 8–10%, have dental check-ups every 12 months and receive one or more fluoride varnish applications and, if necessary, supplementary caries prevention at the clinics. This means that, for the majority of the adolescents, this FRAMM Guideline with school-based fluoride varnish applications constitutes the main part of caries prevention at these ages. In Sweden, there is no fluoridation of the tap water.

Cost-Effectiveness Analysis

A cost-effectiveness analysis aims to provide information about the incremental cost and effect of one intervention compared with the best alternative intervention [Drummond et al., 2015]. This produces a ratio between incremental costs and effects (ICER, incremental cost-effectiveness ratio) produced by the analysed intervention. The cost-effectiveness analysis in this study estimates the ICER of implementing the FRAMM Guideline for various groups, depending on the approximal caries prevalence at the age of 12. The reason why we choose to look upon approximal surfaces is that caries on these surfaces stands for the need of restorations as an adult. Furthermore, fluoride prevention has its best effect on smooth surfaces and the routine to take care of the occlusal surfaces is either by a fissure sealing or, if necessary, by a ground filling. The comparator is the cohort of adolescents born in 1993 who had no fluoride varnish programme at school. The analysis is performed from a societal perspective, covering a 4-year time horizon. The outcome measurements used in the analysis are approximal surfaces with fillings and/or dentin and enamel lesions (decayed and/or filled approximal surfaces, DFSa, and number of approximal enamel lesions, DeSa).

Data Extraction

Caries data for 13,490 adolescents born in 1993 who did not take part in the FRAMM Guideline at school and 11,321 adolescents born in 1998 who followed this guideline from the age of 12 to 15 were previously extracted from dental records in the region, using a script [Bergström et al., 2016a]. For each individual, the following information was extracted: clinic, gender, number of

Table 1. Number and characteristics in the groups

Main group	Sub-group	Total, *n* (%)	Boys/girls, %	Dental check-ups from 12 to 15 years (mean), *n*	High-risk guideline, *n* (%)
Control	low	6,185 (61)	53/47	2.7	–
	moderate	2,962 (29)	50/50	2.7	–
	high	1,013 (10)	47/53	2.8	–
FRAMM	low	7,174 (68)	53/47	2.8	809 (11)
	moderate	2,732 (26)	52/48	2.9	420 (15)
	high	718 (7)	45/55	2.9	137 (19)

Table 2. Approximal caries prevalence in the three groups at the ages of 12, 13, 14 and 15 with and without the FRAMM Guideline

Main group	Sub-group	At age 12		At age 13		At age 14		At age 15	
		DFSa	DeSa	DFSa	DeSa	DFSa	DeSa	DFSa	DeSa
Control	low	0.00	0.00	0.02	0.49	0.06	0.79	0.10	1.16
	moderate	0.33	1.35	0.42	1.70	0.55	2.28	0.68	2.83
	high	1.19	4.72	1.49	4.80	1.96	6.02	2.33	6.40
	all groups	0.22	0.86	0.29	1.32	0.39	1.75	0.49	2.19
FRAMM	low	0.00	0.00	0.01	0.42	0.05	0.55	0.07	0.87
	moderate	0.36	1.28	0.41	1.43	0.53	1.74	0.63	2.25
	high	1.03	5.00	1.25	4.83	1.65	5.11	1.95	6.05
	all groups	0.16	0.67	0.20	1.03	0.28	1.16	0.34	1.58

DFSa, approximal surfaces with fillings and/or dentin lesions; DeSa, approximal surfaces with enamel lesions.

DFSa and DeSa. This was done for each individual and each year, from 2005 to 2008, for those born in 1993 and from 2010 to 2013 for those born in 1998.

The two main groups, with and without the FRAMM Guideline, were further analysed, pooled and separated according to approximal caries prevalence at the age of 12. Those adolescents with no dentin and/or enamel caries lesions and/or fillings were pooled into the "low" subgroup, those with 1–3 caries lesions and/or fillings were pooled into the "moderate" subgroup and those with ≥4 caries lesions and/or fillings into the "high" subgroup, as shown in Table 1.

Those adolescents who not had been examined at the age of 12 were excluded, as their baseline caries experience could not be verified correctly. All the adolescents in the two birth cohorts had attended dental check-ups at their normal dental clinics in the Västra Götaland Region at least once during the age period of 12–15 years. Both cohorts had participants from different geographical areas and with a different caries prevalence and a different socio-economic background.

Cost

Costs were calculated in Swedish kronor (SEK) and converted to euros (EUR) using an exchange rate of SEK 1 = EUR 0.1 (October 16, 2017). The cost of the FRAMM Guideline was based on information from the public dental service in the Västra Götaland Region and related to the reimbursement for the guideline in 2017. This was EUR 12.50 per individual and year (between 12 and 15 years of age) for the application of fluoride varnish and EUR 5.15 per individual for the information on oral health on each of two occasions (12 and 15 years). This totals EUR 60.3 per individual included in the FRAMM Guideline. The time spent on application of fluoride varnish was approximately 1–2 min per individual, and the time spent on information on oral health was approximately 30–40 min per occasion. The cost of fillings was calculated according to the official current pricelist in the region, which is EUR 112.1 per filling. No discounting of costs has been made.

Data Analysis

The data were delivered as Microsoft Excel documents and were analysed using SPSS (version 24) computer software. Descriptive statistics (means and standard deviations) were calculated for each clinical indicator in all the groups, and the differences between the groups were tested by independent-sample tests. $p < 0.05$ was applied for statistical significance.

The effect of the selected measurements was calculated as the difference between the caries increment in the control group and the experimental group divided by the increment in the control group for those that had attended dental check-ups at the age of 12 and the age of 15. This preventive fraction was expressed as percent.

Table 3. Approximal caries increment in the three groups with and without the FRAMM Guideline, calculated for the individuals attending dental check-ups at the age of both 12 and 15 years

	Low subgroup			Moderate subgroup			High subgroup		
	control n = 3,532	FRAMM n = 4,397	p value	control n = 1,684	FRAMM n = 1,681	p value	control n = 615	FRAMM n = 449	p value
Increment (DFSa)	0.10±0.43	0.08±0.43	0.010	0.36±0.99	0.30±0.89	0.042	1.26±1.88	0.99±1.78	0.018
Increment (DeSa)	1.16±2.45	0.87±2.11	0.000	1.45±3.30	0.98±3.13	0.000	1.68±5.12	0.95±4.90	0.020
Total increment (DFSa + DeSa)	1.26±2.58	0.95±2.23	0.000	1.82±3.71	1.27±3.53	0.000	2.93±5.71	1.93±5.38	0.004
Percentage enamel lesions of the total caries increment	92	92		80	77		57	49	

DFSa, approximal surfaces with fillings and/or dentin lesions; DeSa, approximal surfaces with enamel lesions.

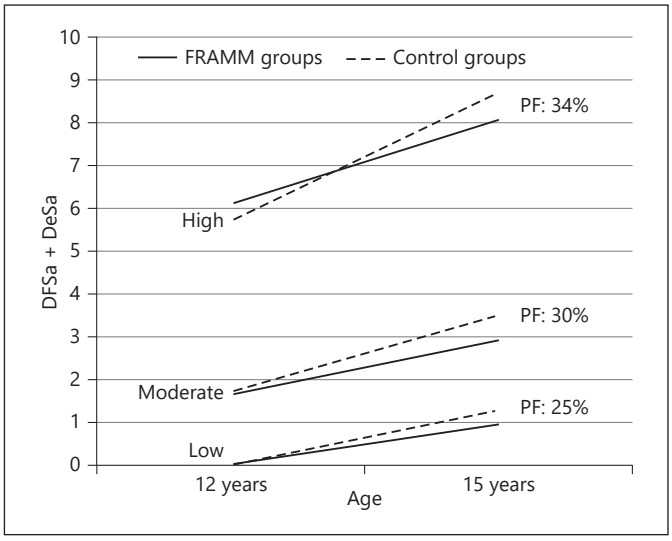

Fig. 1. Approximal caries increment in the groups at examinations at 12 and 15 years and the preventive fraction (PF) in the FRAMM groups.

Ethics

An ethical review of the extraction of data from the dental records was performed and approved by the Regional Ethical Review Board in Gothenburg, Sweden (Dnr: 273-14), prior to the first study by Bergström et al. [2016a].

Results

Approximal Caries Increment

For the total material of 20,784 individuals, the approximal caries prevalence expressed as DFSa and DeSa is presented in Table 2. The low subgroup had a low caries increment for both dentin lesions and fillings and enamel lesions on the approximal surfaces compared with the moderate and high subgroups during the period from 12 to 15 years.

Table 3 shows the approximal caries increment for those individuals with a dental check-up at the age of both 12 and 15. There were statistically significant differences in terms of new approximal dentin lesions and/or fillings, as well as new enamel lesions, between those individuals who took part in the FRAMM Guideline and those who did not, in all three risk groups ($p < 0.05$). Enamel lesions accounted for the main lesions; more in the low subgroup compared with the other subgroups.

Figure 1 shows the preventive fraction in percent in the groups, i.e. treatment effect between the groups with the FRAMM Guideline and the control groups without this guideline. The difference between the groups increases according to the caries prevalence at the age of 12 from 25% for the low subgroup, 30% for the moderate subgroup and 34% for the high subgroup.

Cost and Cost-Effectiveness

The cost of fillings is reduced in the groups with the FRAMM Guideline, due to a reduction in caries increment during the studied period. However, the control groups have no cost for interventions, and the total incremental cost for the groups with the FRAMM Guideline is therefore higher (Table 4).

In Table 5, the cost-effectiveness of the FRAMM Guideline is analysed. This is done by comparing the differences in costs and dividing them by the differences in effects between the FRAMM Guideline groups and the control groups. The cost difference is highest in the low

Table 4. The average participant cost of fillings, the intervention and the total incremental cost in the groups (EUR)

Main group	Sub-group	Cost of fillings[1]	Cost of inter-vention[2]	Total cost[3]	Incre-mental total cost[4]
Control	low	11.8	–	11.8	–
	moderate	40.6	–	40.6	–
	high	140.9	–	140.9	–
FRAMM	low	9.0	60.3	69.3	57.5
	moderate	33.2	60.3	93.5	52.9
	high	110.6	60.3	170.9	30.0

[1] The caries increment (DFSa) from 12 to 15 years multiplied by the cost of a filling (EUR 112.1). [2] The total reimbursement for the FRAMM Guideline from 12 to 15 years. [3] The cost of fillings and intervention. [4] FRAMM versus control.

Table 5. Cost-effectiveness, FRAMM versus control (EUR)

	Subgroup		
	low	moderate	high
ΔC (cost FRAMM-cost control)	57.5	52.9	30.0
ΔDFSa	–0.02	–0.06	–0.27
ΔDeSa	–0.29	–0.47	–0.73
ΔDFSa + DeSa	–0.31	–0.53	–1.00
ICER (cost per prevented DFSa)	2,875	882	111
ICER (cost per prevented DeSa)	199	113	41
ICER (cost per prevented DFSa + DeSa)	186	100	30

DFSa, approximal surfaces with fillings and/or dentin lesions; DeSa, approximal surfaces with enamel lesions; ICER, incremental cost-effectiveness ratio.

subgroup and lowest in the high subgroup. The ICER is calculated for DFSa, DeSa and DFSa and DeSa together. The analysis revealed the lowest ICER for the high subgroup for DFSa and DeSa together (EUR 30) and the highest ICER for the low subgroup for DFSa alone (EUR 2,875). The statistical uncertainty surrounding these results is very low due to the use of a fixed pricelist of costs and a very large sample. However, changes in the pricelist would have some impact on the results. For example, if the pricelist were 20% higher, the ICER for the high subgroups for DFSa alone would increase from EUR 111 to 133.

The incremental cost-effectiveness ratios for FRAMM compared with controls for DFSa and DeSa together is illustrated in a cost-effectiveness plane in Figure 2. Here,

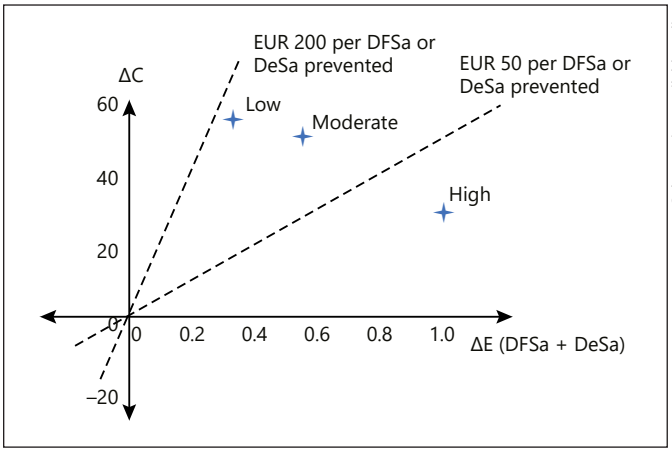

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Fig. 2. Incremental cost-effectiveness ratios presented in a cost-effectiveness plane, FRAMM versus control, for the low, moderate and high subgroups. ΔC, change in costs (EUR); ΔE, change in effects (DFSa + DeSa); DFSa, approximal surfaces with fillings and/or dentin lesions; DeSa, approximal surfaces with enamel lesions.

it can be seen that the results differ a great deal between the studied subgroups. Even if no official threshold value exists, we have plotted two such thresholds at EUR 50 and 200 per DFSa or DeSa prevented. If the lower threshold is used, FRAMM is only cost-effective for the high subgroup, but, if the higher threshold is used, FRAMM is cost-effective in all subgroups.

Discussion

The evaluation of the FRAMM Guideline with fluoride varnish application at school implemented for all 12- to 15-year-olds showed that the caries prevalence at the age of 12 predicted the approximal caries increment during the next 3 years. The individuals with the highest caries prevalence at 12 years of age who took part in the interventions according to the guideline had 34% less caries on their approximal surfaces compared with those individuals who did not take part. Moreover, the individuals who were caries free on the approximal surfaces at the age of 12 and took part also gained compared with those caries-free individuals who did not take part. According to our results, implementing FRAMM, assuming risks similar to those in our study, would lead to an additional cost of EUR 55 per participant for the analysed period of 4 years.

It is possible to discuss whether a guideline of this kind should be implemented on a population-based level or only for those individuals with a confirmed high risk of

caries. Based on the cost-effectiveness ratios in our study, it might be tempting to suggest only including FRAMM for the high-risk group. However, this would lead to the cost per participant rising, and the drop-out rate would probably be high, so our analyses cannot be interpreted like this. The results of the present study, with a preventive fraction between 25 and 34% in all groups, instead stresses the importance of a population-based strategy instead of a high-risk strategy, which is in accordance with earlier studies [Batchelor and Sheiham, 2006]. There are many explanations for this, including the difficulty selecting individuals who will suffer from caries in the future and the fact that the best single predictor of new caries lesions is previous caries lesions, which means that the individual is not caries free [Mejàre et al., 2014]. The optimal situation is to implement a guideline like FRAMM at an early age, when the approximal surfaces are still caries free, which means that they are also free from enamel lesions. During the period between 12 and 15 years of age, many surfaces are at risk, in combination with adolescents adopting poorer drinking and eating habits that will increase the caries risk. In the present study, it was obvious that the guideline had a better effect on keeping upcoming enamel lesions within the enamel in the low subgroup compared with the moderate and high subgroups, which also underlines the fact that caries prevalence at baseline predicts upcoming caries at caries risk ages.

Previous experience has shown that there is a challenge when it comes to transferring evidence-based dentistry into clinical practice [Bonetti and Clarkson, 2016]. Caries prevention guidelines are incredibly important when tackling this problem. However, when implementing a guideline like this, it is important to control compliance. In the Childsmile Project from Scotland [Macpherson et al., 2010], only 8% of the children in 2010/2011 received a second fluoride varnish application, which is far from optimal [Central Evaluation and Research Team, 2012]. The evaluation from the present FRAMM Guideline shows that 99% of the school classes in grades 6–9 follow the recommendations [Bergström et al., 2016a].

A somewhat surprising finding was that it appeared to be very small differences between those with and without caries experience, in number of dental check-ups. Nevertheless, this phenomenon is also shown in other counties in Sweden according to SKaPa [2016].

The effects of health interventions have mostly focused on answering the question "What works?" and have not aimed to determine whether the intervention is worth performing according to the available resources. It is therefore important to incorporate economic perspectives in evaluations of health interventions [Shemilt et al., 2013]. When implementing a guideline, its cost-effectiveness has to be taken into consideration. Is it viable and worthwhile to let all 12- to 15-year-olds take part? In the previous study by Bergström et al. [2016a], the FRAMM Guideline was found to have contributed to a low caries increment at a low cost. In that study, all the adolescents in two birth cohorts were analysed without considering any subgroups. The results of the present study, where subgroups with different caries prevalence were analysed, showed that the lowest ICERs were found in the high and moderate subgroups. It is interesting to ask how much society is willing to pay for a reduction in caries and, furthermore, what the resources could otherwise have been used for. There is no threshold value for willingness to pay per DFSa or DeSa prevented. However, some guidance can be given by using an earlier example of cost-effectiveness threshold values made by the Swedish National Guideline for Adult Dental Care [The Swedish National Board of Health and Welfare, 2011]. In this example, it is stated that dentin caries lesions, 1 DMFS, prevented below EUR 100 is assumed to be a low cost, below EUR 200 is moderate, below EUR 500 is high and costs above EUR 500 are regarded as being very high. This means that FRAMM could be considered to produce a low or moderate cost for the subgroup with a high risk but with less attractive cost-effectiveness for subgroups with a low or medium risk.

Another aspect that affects the interpretation of cost-effectiveness is the outcome measurement that is used. If our study had had a broader quality-of-life outcome measurement, such as quality-adjusted life-years, its cost-effectiveness could more easily have been compared with other studies and previous decisions made for areas other than dental care. An outcome like this might, furthermore, have captured other aspects of oral-related quality of care. However, so far, no study has shown the relationship between DMFS and a valid quality-adjusted life-years weight. Finally, the cost-effectiveness of FRAMM would probably have been improved if a longer time horizon had been used for the analysis, as reduced caries within the studied time frame would probably affect the future incidence of new caries, as fillings may generate costs in the future. Doing this would, however, involve modelling costs and consequences far from the studied time frame, something that was beyond the aim of this paper.

The cost-effectiveness results of implementing FRAMM could be compared with other analyses. A recently published German study with fluoride varnish ap-

plication twice yearly in 6- to 18-year-olds from different caries risk groups showed no cost-effectiveness in low-risk individuals in a clinic setting [Schwendicke et al., 2017]. This study suggested that fluoride varnish application has to be provided at a lower cost, which our study underlines, i.e. individuals in groups at school and by dental nurses. In a study from the Netherlands, the cost-effectiveness of two caries prevention programmes with increased professional fluoride application and non-operative caries treatment and prevention, respectively, among 6-year-old children was analysed compared with standard care that already consisted of twice a year dental check-ups, fluoride application and preventively placed sealants of first primary molars [Vermaire et al., 2014]. In this study, none of the interventions reduced costs in comparison to regular dental care, but the latter intervention had the most favourable ICER (EUR 100 per DMFS saved compared with regular dental care from a societal perspective). However, in the study from the Netherlands, few surfaces were at risk, as the study only included 6-year-olds, compared with our study where the individuals have many surfaces at risk. In terms of the cost-effectiveness of fluoride varnish programmes, a recently published study of a community oral health programme compared fluoride varnish with fissure sealants in caries-free 6- to 7-year-olds in an area with a high caries risk in Wales. No differences in caries prevention effect were found, but fluoride varnish proved to be less expensive and probably more cost-effective in the longer perspective [Chestnutt et al., 2017].

To implement this guideline in the most efficient way, the school is an obvious dental health arena, as the interventions can be performed with groups of individuals instead of individually in a clinic setting. Choosing the most efficient group of dental personnel means dental nurses rather than dental hygienists or dental physicians. Dental nurses in Sweden have been working on caries prevention in children and adolescents since the 1960s, both at dental clinics and outside at child health centres and schools. The term "prophylactic dental nurse" originates from the mid-1970s, when dental nurses took part in special courses on dental health prevention for children and adolescents. Today, this is incorporated in the standard education and is a common task for all dental nurses. A previous study performed in the Västra Götaland Region revealed that dental nurses were pleased to work with adolescents at school, as they do according to the FRAMM Guideline [Bergström et al., 2016b].

Seeing adolescents regularly at school at caries-risk ages gives the dental personnel an opportunity to stimulate good self-care in relation to toothbrushing with fluoridated toothpaste and eating and drinking habits. A previous study has shown that the adolescents had a positive attitude to dental personnel coming to school [Bergström et al., 2012].

With this population-based strategy, there will be individuals who are free from caries with or without the intervention, but, as long as the interventions do not harm anyone, everyone should have the opportunity to take part. This is also essential from a democratic point of view. The efforts at school involve more than applying fluoride, such as oral health education, but distinguishing between the effect of every single effort is difficult. However, dental health guidelines without any form of fluoride therapy fail to achieve any caries reduction and, for this reason, lecturing alone is not a good alternative [Kay and Locker, 1998; SBU, 2002].

Finally, it would be of interest to further evaluate the FRAMM Guideline to see whether there is any long-term effect on approximal caries increment and cost-effectiveness up to the age of 20 or more.

To conclude, this study showed that the FRAMM Guideline significantly reduces the caries increment for adolescents with a low, moderate and high caries prevalence, when implemented under field conditions on a broad scale. Furthermore, the subgroup which showed the most favourable cost-effectiveness was the one with a high caries prevalence at the age of 12.

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Disclosure Statement

There are no conflicts of interest.

Author Contributions

All three authors contributed to the design of the study, the analysis and interpretation of data as well as writing and revising the manuscript.

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