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ORIGINAL ARTICLE

Economic evaluation of an expanded caries-preventive program targeting toddlers in high-risk areas in Sweden

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ABSTRACT

Objective: To economically evaluate a caries-preventive program "Stop Caries Stockholm" (SCS) where a standard program is supplemented with biannual applications of fluoride varnish in toddlers and compared it with the standard preventive program.

Material and methods: Data from the cluster randomized controlled field trial SCS including 3403 children, conducted in multicultural areas with low socioeconomic status was used. The difference in mean caries increment between the examinations; when the toddlers were 1 and 3 years old, was outcome measure of the intervention. The program was evaluated from a societal as well as a dental health care perspective. The incremental cost-effectiveness ratio (ICER) was calculated as the incremental cost for each defs prevented.

Results: Average dental health care costs per child at age 3 years were EUR 95.77 for the supplemental intervention and EUR 70.52 for the standard intervention. The ICER was EUR 280.56 from a dental health care perspective and EUR 468.67 and considered high.

Conclusions: The supplemental caries intervention program was not found to be cost-effective. The program raised costs without significantly reducing caries development. A better alternative use of the resources is recommended. Trial registration: www.controlled-trials.com (ISRCTN35086887).

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Introduction

Oral health of toddlers has improved over the last few decades in Sweden [1], but this improvement has bypassed some children. More often than native-born residents, immigrants live under low socioeconomic conditions [2], and low socioeconomic status is significantly associated with a higher risk of developing dental caries [3]. In 1995, one study surveyed and reported discrepancies in the oral health of children living in Stockholm: among 3.5-year-olds, caries prevalence in toddlers with an immigrant background was 63% compared with 26% in those with a non-immigrant background [4]. Another Swedish study reported the same pattern in 2008 where 59% of 4-year-old children with an immigrant background had developed dental caries compared with 32% of native-born children in Umeå [5].

Caries-prevention programs based on fluoride varnish have shown good efficacy [6]. However, recent published data report insufficient effectiveness when used as a supplement to a standard caries-prevention program in high-risk children [7]. Despite this, fluoride varnish is still being recommended as a preventive measure for young patients [8, 9].

Although use of fluoride varnish in some programs is clinically effective, it should also be cost effective; public resources are limited and ideally used only in social programs that have proven cost effectiveness. Recent systematic reviews indicate that the number of economic evaluations in dentistry are increasing [10], but the need is still large, and more work in this field is necessary. A recent report on scientific evidence in pediatric dentistry identified a knowledge gap concerning the management of dental conditions and their cost effectiveness [11]. Marihno et al. (2013) concluded that there is a need for methodological quality improvements in reporting economic evaluations of caries-preventive programs [12]. Report standards for economic evaluations are now available to support researchers [13].

The Stockholm County Council in Sweden manages the resources for preventing dental caries in children. Due to persisting inequalities in the caries status of toddlers in the various socioeconomic groups, a study was conducted to evaluate the clinical effect and the cost effectiveness of an expanded preventive program. The clinical trial focused on early prevention for 12–36-month-old toddlers living in high-risk areas. The program was designed as a parallel cluster-randomized controlled trial and was conducted under the working name Stop Caries Stockholm (SCS). All participating children received a standard caries-preventive program for oral health with yearly visits that include hands-on tooth brushing instructions to the parents with feedback, information about tooth-brushing twice daily with fluoride

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toothpaste, and dietary counselling focusing on drinking water as a healthy alternative to other thirst-quenchers and reducing the frequency of between-meal snacking. In addition to the visit, the parents also received a toothbrush and toothpaste (1000 – 1450 ppm fluoride) free of charge.

The toddlers in the test group received supplemental measures in an expanded program, which comprised fluoride varnish treatments every half year in conjunction with standard caries-preventive measures. No significant effect on the development of dental caries was found at the 2-year evaluation when the toddlers were 36 months old [7]. The aim of this study was to do an economic evaluation of the expanded caries-preventive program and compare it with the standard program already in place.

Material and methods

Interventions and participants

This study uses SCS data from the longitudinal, cluster-randomized field trial conducted between March 2011 and March 2014. The Regional Ethics Committee in Stockholm approved the study (daybook no. [Dnr] 2010/1956), which was registered at www.controlled-trials.com [ISRCTN35086887]. The trial involved toddlers living in multicultural areas with medium-to-low socioeconomic status in Stockholm, Sweden; these areas are also considered risk areas for dental caries due to the high prevalence of dental caries. One of the main goals of the trial was to reduce inequality in the oral health of the children in the county. The toddlers were allocated to either a reference group or a test group. In a stratification process, each participating dental clinic ($n = 23$) had been allocated into two groups taking into account earlier caries risk data of the clinic. Efforts were made to achieve an equal distribution concerning the number of children in the groups and geographic location of the dental clinics. By drawing lot the intervention to be given was decided. Between ages 12 and 36 months, the toddlers received standard interventions, which included support to the parents for establishing home care routines. These routines focused on tooth-brushing twice daily with fluoridated toothpaste; reducing between-meal snacking; and encouraging the parents to give their child water to drink, instead of sugar-containing drinks, when thirsty. This intervention was given once a year to the reference group and twice a year to the test group Additionally, the test group received fluoride varnish treatments on all erupted teeth (Duraphat®, 22.6 mg of fluoride per ml, Colgate-Palmolive) at all intervention visit. All toddlers were given a free toothbrush and toothpaste at each intervention visit (1000–1450 ppm fluoride). For a full description of the trial, please see previously published data [7].

The clinicians, with the parents, filled in a form with questions about the toddler's social condition, general health, and dietary and tooth brushing habits. The clinician collected this information at the first intervention (baseline data) when the toddlers were 12 months, but also at the yearly examinations.

Outcomes

We used the International Caries Detection and Assessment System (ICDAS II, hereafter referred to as ICDAS) to record dental caries [14]. This detailed system more thoroughly follows the various stages of caries progression than the defs system currently in wide use. ICDAS dental caries scores were then translated to the WHO criteria for cavitation as recommended by Braga et al. [15]. A tooth surface that was recorded as ICDAS 0 – 2 was regarded as non-cavitated and a tooth surface with an ICDAS score of 3 – 6 was regarded as cavitated. ICDAS score 3 also includes enamel surface breakdown not exposing dentin. Except for the cavitated surfaces, the calculations included only surfaces in teeth extracted due to dental caries and surfaces in which a filling had been placed. Information on the development of dental caries (defs) was extracted from the 1- and 2-year examination data of the SCS trial and used as a single outcome measure to assess program effectiveness. All toddlers were investigated by calibrated examiners at the dental clinics, as described by Anderson et al. (2016). Based on clinical examination of a sample of 20 toddlers with ICDAS score of 3 as the cut-off for cavitation the mean inter-examiner agreement score was $\kappa = 0.61$ at the first examination and $\kappa = 0.73$ at the second examination two weeks later.

Resource use

Intervention program costs were calculated in Swedish Crowns (SEK). Euro (EUR) was determined using the 19 May 2017 exchange rate: SEK 1 = EUR 0.10 [16]. All costs were adjusted to 2011 year price levels and discounted by 3% annually from the second year of the intervention period, according to Swedish government guidelines [17].

The cost analysis included determining intervention program costs and individual miscellaneous costs for each child during the study. Intervention program costs included the time each member of the dental team spent for the clinic visits. Salary costs of the dental personnel were estimated using public lists of the median salaries for Public Dental Service personnel in Stockholm County, including social taxes and fees. Thus, the analysis used costs of EUR 0.60/min for dentists, EUR 0.45/min for dental hygienists, and EUR 0.38/min for dental assistants.

Twenty minutes were planned for each visit, which included 5 min for administrative routines. For the baseline and 1-year examinations, it was assumed that the dental hygienist would need 20 min. For the 2-year examination, that the dental assistant would need 20 min and the dentist 10 min. All toddlers in the test and reference groups were offered examinations at ages 12, 24, and 36 months as described here. The test groups were offered additional visits at ages 18 and 30 months, which comprised 20 min of time for a dental assistant. Table 1 summarizes the number of visits for each group and the time spent by each member of the dental team.

Intervention costs also included standardized costs for fluoride varnish (EUR 0.36), tooth brushes (EUR 0.75), toothpaste (EUR 1), and postal invitations by land post (EUR 1) per child for each single intervention visit. Overhead costs were calculated for each intervention year as 50% of the other intervention costs to account for head office and related common costs of the clinic, such as office staff, and software and other licenses, consumables, and premise rental. The method we used was recommended in the 2008 Swedish Dental Care Reform [18].

To analyze the cost of dental care due to caries during the interventions, we selected a sample of toddlers in the SCS trial and gathered data from their dental records. Three dental clinics for each intervention group were chosen. These clinics were the ones who were the first to complete the 2-year intervention. We analyzed data from 658 dental records in the test group and 688 dental records in the reference group. Costs due to missed appointments were calculated. Production loss due to a missed appointment was estimated at EUR 6.0 as we assumed that the dental personnel would use some of the time for other activities connected to their work. Any toddler who missed a scheduled intervention was sent an invitation for a new visit. Data on number of non-intervention visits due to dental caries and the time the visits consumed were also extracted from the records. We used the PDS price list from 2011 for dental care in Stockholm County to determine the costs of the non-intervention visits at the participating PDS clinics. For non-intervention visits at the specialist clinics, the price list for specialist pediatric dental care was used.

In the final step, we summarized all extracted costs and divided the sum by the number of toddlers. Because we had also extracted information on the number of missed intervention visits, we were able to adjust our calculation of health care costs to compensate for this.

We defined indirect costs as parental investments in terms of time: waiting time, intervention time, and travel. We estimated 7 min for waiting time, 15 min for the intervention visit, and 30 min for travel, which is a total of 52 min. We used the Vermaire et al. [19] estimate of average waiting time. Five minutes of the 20-min intervention was intended for dental staff use for cleaning up and administrative routines. Oscarson et al. [20] used a Swedish survey to estimate average travel time in Stockholm. The true cost of parental time was difficult to estimate; we assumed that most parents scheduled the intervention visits during unpaid time, which we valued as EUR 12.50 per hour, as did Vermaire et al. [19]. We included no costs for project management in the analysis.

Table 1. Number of visits and time each member of the dental team spent with individuals in the test (standard intervention + supplemental measures) and reference (standard intervention) groups.

Group	Visits (number)	Dental assistant (minutes)	Dental hygienist (minutes)	Dentist (minutes)	Total (minutes)
Test	5	60	40	10	110
Reference	3	20	40	10	70

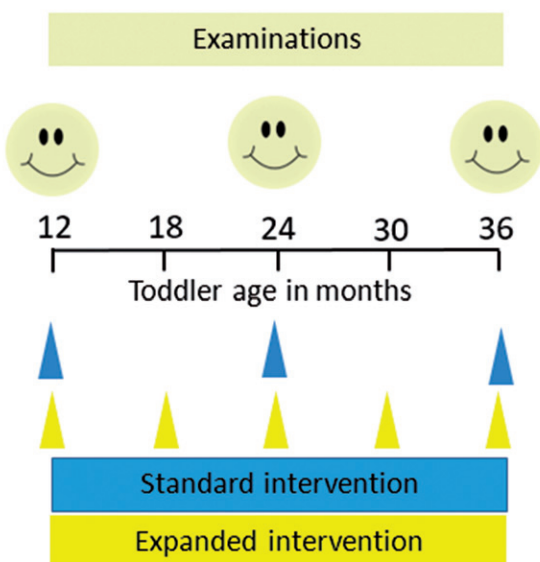

Figure 1. Illustration of intervention timing in the two study groups: the test (standard intervention + supplemental measures) and reference (standard intervention) groups.

Cost-effectiveness analysis

A cost-effectiveness analysis aims to provide information about the incremental cost and effect of one intervention compared to the best alternative intervention. The outcome of this analysis is the incremental cost-effectiveness ratio (ICER), a ratio between incremental costs and effects of the analyzed intervention compared to standard care.

The cost-effectiveness analysis in this study estimates the ICER of a supplemental intervention program compared to a standard intervention already in place among toddlers living in high-risk areas of Stockholm County (Figure 1). We made the analysis from two perspectives: a dental healthcare perspective and a societal perspective. The primary measure for effects is number of defs prevented. Hence, the analysis estimates the additional cost of preventing 1 defs. Figure 2 presents the general structure of the analysis.

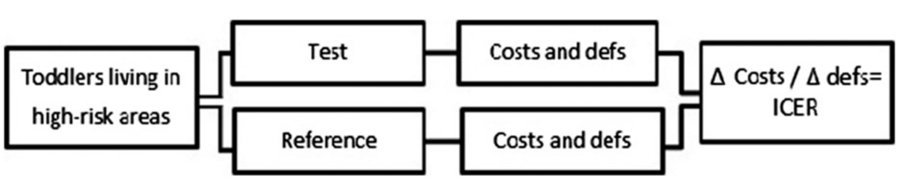

Figure 2. Flow chart illustrating calculation of the incremental cost-effectiveness ratio (ICER) comparing a test group (standard intervention + supplemental measures) and a reference group (standard intervention). ICER is the ratio between the incremental costs and the effect (number of decayed missed and filled surfaces in primary teeth [defs]).

Statistics

All data were processed in Microsoft Excel 2013 and IBM SPSS Software (version 21.0). The Chi-square test assessed differences in caries prevalence, while the unpaired *t*-test analyzed differences in defs at 36 months and in the 12–36-month defs increments (Δ) between the test and reference groups. We considered a *p*-value less than .05 as statistically significant.

Results

Participants

In the longitudinal trial, 3403 toddlers enrolled at baseline: 1652 toddlers in the test group and 1751 in the reference group. The test and the reference groups were balanced considering background characteristics as recorded by the questionnaire. At the follow-up 2 years later, 75% ($n = 2536$) of the toddlers were re-examined. A flow-chart of patients in the study can been seen in Anderson et al. (2016) [7]. The main reason for dropping out was relocation outside of the study area [7].

Effect of treatment

At age 36 months, no significant difference in caries prevalence or defs had occurred between the test and the reference groups (Table 2). The difference in mean increment between the groups from baseline at 12 months of age to the follow-up at 36 months was 0.09 defs in favor of the test group. Discounting second-year effects by 3% did not change the defs increment. We used 0.09 as the base case effect measure in calculating ICER.

Resource use

Table 3 presents the average intervention costs, additional treatments costs as extracted from the dental records, and the indirect cost calculation per child. We calculated the health care costs used in the later analyses by combining the intervention costs with the additional costs. Indirect costs were adjusted for missed intervention visits to account for less parental time.

Additional and missed dental visits

The average number of unscheduled clinic visits outside of the study due to dental caries was 0.03 per child in both groups. The time used was 0.58 min per toddler in the test group and 0.39 min per toddler in the reference group.

Not all toddlers attended the dental clinics as planned during the 2-year intervention program. The test group was scheduled for 5 visits, and the toddlers missed 17% of these (0.74 visits per child). The reference group was scheduled for 3 visits, and the toddlers missed 13% of these (0.40 visits per child).

Table 2. Prevalence of dental caries (defs >0 and defs at age 36 months) and defs increment (Δ) between ages 12 and 36 months for the test (standard intervention + supplemental measures) and reference (standard intervention) groups.

	Expanded intervention	Standard intervention	Confidence interval 95%
defs >0	10.8%	13.3%	–
defs (SD)	0.64 (2.9)	0.69 (2.8)	−0.17; 0.27
Δ defs (SD)	0.59 (2.8)	0.68 (2.8)	−0.13; 0.30

Table 3. Mean costs (EUR) per child in the test (standard intervention + supplemental measures) and reference (standard intervention) groups.

	Costs (EUR)	
Items	Test group	Reference group
Intervention costs		
Fluoride varnish	1.84	0
Toothpaste	5.12	3.08
Toothbrush	3.84	2.31
Postal invitation	5.12	3.08
Dental hygienist	15.22	15.22
Dental nurse	19.47	6.57
Dental surgeon	5.41	5.41
Overhead	24.89	14.97
Total intervention costs	80.92	50.66
Additional costs		
Incomplete intervention visits	−3.94	−1.93
Missed appointment	3.89	2.93
Specialist clinic	13.98	16.19
Non-intervention visits	1.22	2.26
Total additional costs	15.15	19.46
Total dental health care costs	**96.08**	**70.12**
Indirect costs	43.50	26.57
Total costs	**139.58**	**96.69**

Table 4. Incremental cost-effectiveness ratio (ICER) for the test (standard intervention + supplemental measures) versus reference (standard intervention) groups from two perspectives.

	Perspective	
Test vs. reference groups	Dental health care system	Societal
Δ costs (EUR)	25.25	42.18
Δ effects (defs)	0.09	0.09
ICER	280.56	468.67

During the 2-year period, some toddlers visited a specialist pediatric dental clinic. The test group made 0.10 visits per child and the reference group, 0.04 visits per child. The specialist clinics reported no missed appointments.

Interpreter costs

We found that neither the test nor the reference group used an interpreter regularly. The reference group used an interpreter for 1.6% of the total number of visits made by the toddlers. The corresponding value for the test group was 0.37%. Using an interpreter would raise costs, but low use and an insignificant, between-group difference in use allowed us to exclude interpreter costs in the analyses.

Cost-effectiveness

Table 4 illustrates how the expanded intervention program led to higher per-child costs compared with the intervention already in place: EUR 24.86 from a dental health care perspective and EUR 41.79 from a societal perspective. A cost-

Table 5. Sensitivity analysis showing change in incremental cost-effectiveness ratios (ICERs) from a dental health care system perspective (DHCP) and a societal perspective (SP) for various scenarios.

	Incremental cost (EUR)		Incremental	ICER	
Scenario	DHCP	SP	defs	DHCP	SP
No effect assumed	25.25	42.18	0	Dominated	Dominated
Effect					
Worst case	25.25	42.18	−0.13	Dominated	Dominated
Best case	25.25	42.18	0.30	84.17	140.60
Discounting effect 0%	25.25	42.18	0.09	280.56	468.67
Discount rate					
0%	25.39	42.32	0.09	282.11	470.22
5%	25.15	42.08	0.09	279.44	467.56
Overhead (25%)	20.29	37.22	0.09	225.44	413.56
Travel time (0 minutes)	–	31.22	0.09	–	346.89

All costs are in euro (EUR).

effectiveness analysis requires that this additional cost to be weighed against the impact of the program. Table 4 presents the ICERs for both programs.

Sensitivity and scenario analysis

Changes in effects and cost items may affect the cost-effectiveness analysis. Table 5 presents various scenarios. To calculate the best- and worst-case scenarios for effect, we used the top and bottom values of the 95% confidence interval for difference in defs. Because no significant difference in effect occurred between the programs, we found no effect that would allow the supplemental program to dominate the standard program. The worst-case scenario for effect would also allow the standard program to dominate the expanded program. The best-case scenario for effect would reduce the ICER considerably, both from a dental health care perspective and a societal perspective. Changes in discount rates (costs and effects) had a negligible effect on the ICERs. Neither did reducing overhead costs affect the ICERs. Less travel time or waiting time for the parent accompanying the toddler would improve the ICER from a societal perspective.

Discussion

The economic evaluation comparing the expanded caries-prevention program with the standard caries-prevention program already in place showed that it would be difficult to view the expanded program as cost effective. The expanded program, including more regular dental visits and application of fluoride varnish twice a year, raised program costs to between EUR 280.56 and EUR 468.67 for each prevented defs. The study was conducted in toddlers between ages 1 and 3 years who lived in high-risk areas of Stockholm County for developing caries.

Tickle et al. used a similar intervention concept in their study of somewhat older preschoolers in Northern Ireland [21]. The children had a mean age of 3.1 when the program started and had no decayed surfaces at baseline, and as in our study, no intervention was able to halt the development of dental caries. They found, as did we, an insignificant between-group difference in the proportion of children developing dental caries. Contrary to our results, however, they reported a statistically significant 34% relative reduction in defs in the intervention group with an average 2.43 fewer affected tooth surfaces. For the 3 years of the intervention, the mean estimated cost per avoided carious surface was £251.00. The GBP/EUR exchange rate of 1.18 (15 May 2017) [16] yields a cost of EUR 296.18, which was below our cost considering their study was 50% longer than ours.

In Sweden, Wennhall et al. conducted a 3-year prevention program in multicultural areas with a low-socioeconomic status from age 2 years; the program had a direct per-child cost of EUR 310. Compared to intervention costs of EUR 51.77 – 80.92 per child in our 2-year study, our costs for the expanded intervention group must be considered lower. The Wennhall et al. study found a mean caries prevalence of 8.2 defs in the intervention group compared to 11.2 defs in the reference group. They estimated a savings equivalent to three one-surface fillings per child and calculated a net program cost of EUR 30 per child [22].

None of the studies has a threshold value for willingness to pay per defs prevented, which means that it is not possible to clearly say whether an effective treatment is cost effective or not. However, the Swedish National Guidelines for Adult Dental Care [23] suggest threshold values for the cost effectiveness of a saved defs. A cost per saved defs of < EUR 120 is considered low; of EUR 120 – 240, moderate; of EUR 240 – 600, high; and of > EUR 600, very high. This means that the evaluated program, in the most optimistic of scenarios, has a high cost per saved defs. Although these thresholds were calculated for permanent teeth, the thresholds may act as guidance until threshold values for primary teeth are developed.

Another drawback in our study is that we only used a one-dimensional measurement (defs) to evaluate the intervention programs. It would have been more accurate to include instruments that measure how the interventions interfere with the quality of life [24]. Our results would then have been easier to compare with other health sectors.

Because the randomized controlled trial recorded no information on indirect costs, we made assumptions. Assumptions for parental time as well as choosing to estimate parental time as unpaid work may be regarded as rough. But we think it is important to include these indirect costs in the analyses as they widen perspective and show that not only health care resources are involved. The Dental and Pharmaceutical Benefit Agency in Sweden recommends a societal perspective [25]. Another strength of our study is that most of the data were derived from a clinical trial that was also randomized, making it possible to calculate true health care costs for a large part of the analyses. The evaluation considers not only the interventions costs for each toddler but also other costs related to dental caries that arose during the intervention. This makes possibly a fuller picture of the costs for treating dental caries in young children, which is valuable information for dental health planners. Our study reports information on missed dental appointments, and we found a tendency on the individual level for a higher rate of missed appointments in the test group with more frequent visits, which should be taken into consideration when adding dental visits to a prevention program.

One interesting finding in the dental records was the sparse use of an interpreter. As use of an interpreter is free of charge for both the patients and the dental clinic in Sweden, cost should be no obstacle. One explanation of the sparse use might be the multicultural origin of the dental staff. Regardless, these findings should make us pause to consider whether more regular use of an interpreter would be beneficial. Language difficulties may cause insecurity in the recipient of the preventive message, which would undermine the success of the intervention [26].

One question readers might ask is why it is necessary to spend time calculating the cost effectiveness of a program that yields an insignificant effect. Because public resources are limited, the use of economic resources play an integral part. A health economic analysis supports policymakers in decisions on whether to implement new interventions. It is also important to assess the costs and effects of programs that are already in place. An intervention might be effective, but not cost effective. If the intervention had been proven more effective or less costly than the program already in place, policymakers would have considered implementing an expansion of the existing caries-prevention program in Stockholm County. To consider, is also that, in this study many preventive efforts were already being made in the existing standard intervention. Highlighting the importance of preventive interventions is crucial. Even if we showed no effectiveness of the supplementations, we must continue to strive for better caries-preventive care. To minimize the differences in oral health and achieve equality in our targeted high-risk groups with the rest of the Swedish population, other methods are needed.

Many times, interventions are implemented based on efficacy studies and other populations. This study shows the importance of evaluating ongoing efforts already in place. We had anticipated that the supplemental intervention would be effective and that it would be beneficial to put into clinical practice. But evidence-based medicine is about facts and proof, not belief. The evidence did not support our anticipations.

Dental caries is a multifactorial disease [27] and, thus, requires a multifactorial approach. We plan to further analyze our effectiveness results to see if any subgroup gained from the intervention. Future research on children who miss their appointments is also needed. For these children, dental healthcare alone might not be able to change their situation. To reach these children, new networks with other health sectors and professions that see these children in their everyday life might be needed.

From a societal perspective, we need more supportive actions. To improve the oral health of vulnerable children, we cannot depend solely on the actions of caregivers, we must set in other actions in parallel. One intervention that was effective in reducing dental caries as well as allow inequalities in the oral health of children to be monitored was the nursery tooth-brushing program in Scotland [28, 29].

In a wider perspective, more radical societal actions also might be possible. Schwendicke et al. [30] estimated how a taxation of sugar-sweetened beverages would influence caries development. They found that such a taxation might possibly have a vague impact on reducing the caries increment overall, but the effect would interfere with equality as the best oral health results would probably be achieved in young low-income males.

In conclusion, our economic evaluation found that the expanded caries-preventive program we designed, with the aim of improving the oral health of toddlers living in multicultural areas in Stockholm with a low-socioeconomic status, cannot be considered cost effective. Application of fluoride together with a standard program delivered every half year to toddlers between 1 and 3 years of age did not significantly reduce caries development. The program also increased costs from both health care and societal perspectives, indicating a need for a better alternative use of resources. The article gives example of other possible preventive actions to further investigate.

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Disclosure statement

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