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A randomized controlled trial of cluster audit and feedback on the quality of dental sealant for rural schoolchildren

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The objective: To examine whether audit and feedback could improve the quality of the application of dental sealant in rural Thai school children. ***Research design:*** A single blind, cluster randomized controlled trial was conducted. ***Clinical setting:*** Hospital-based and school-based school sealant applied by dental nurses in Southern province of Thailand. ***Participants:*** Dental nurses and school children who received dental sealant were involved. ***Intervention:*** The intervention consisted of confidential feedback of data and tailor-made problem-solving workshops. ***Main outcome measures:*** Sealant quality was measured by sealant retention and caries on sealed surfaces at six-month after sealing. The teeth examinations were done among different groups of children prior and after the intervention. ***Results:*** After the intervention, the sealant retention rate increased dramatically in the intervention group, whereas in the control group the rate was similar to that found at baseline. The rate of caries after the intervention was stable in the intervention group and increased slightly in the control group. At the beginning of the study, the adjusted odds ratio of complete sealant retention between the intervention and control group was 0.47 which increased to 1.99 at the end of the study. However, no effect on caries on sealed surfaces was observed. ***Conclusions:*** The intensive focus on actual problems during the audit and feedback improved the dental nurses' performance and the quality of the dental service, although it had no statistical impact on the incidence of caries.

Key words: *audit and feedback, dental sealant, quality of service, dental caries, school children, Thailand*

Introduction

The World Health Organization has set the goal for health systems of providing quality care equitably (World Health Organization, 2000). Oral health exemplifies the inequality which exists in access to quality care and there have been several studies of such problems in different countries (Hosseinpoor *et al.,* 2012; Somkotra *et al*., 2009). National universal coverage in Thailand has still not solved the problem of inequality of oral health especially for children (Dental Division, 2012). To alleviate dental caries, the school dental sealant program recommended by the American Association of Community Dental Programs, was launched in Thailand more than ten years ago (AACDP, 1995). The effectiveness of the sealant is high among high caries risk children (Ahovuo-Saloranta *et al*., 2013). However, in Thailand and some other countries, there are problems of quality of sealant especially among deprived children in rural areas who have poor sealant retention and high caries on sealed surfaces (Tianviwat *et al*., 2008). Thus there is a need to improve sealant quality.

A widely used strategy to improve the performance of physicians is "Audit and feedback", defined as a "*quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change*" (NICE, 2002). The Cochrane Database of Systematic Reviews concluded that "*Audit and feedback generally leads to small but potentially important improvements in professional practice*" but despite more than 140 reported randomized control trial studies (RCTs) on audit and feedback there are few in the dental health field (Ivers *et al.*, 2012).

An earlier qualitative study reported changes in dental nurses' awareness immediately after receiving audit and feedback information (Tianviwat *et al.,* 2015). The objective of the current study was to evaluate the efficacy of the audit and feedback system implemented among groups of dental nurses to improve the quality of the dental service given to rural children.

Materials and methods

This quantitative study aimed to identify changes in dental nurses' performance in terms of sealant retention and caries on sealed surfaces among sealed children. The study was implemented in Songkhla province in southern Thailand where 15 eligible contracting units for primary care (CUPs) administered sealants in rural areas. However, three of the CUPs were excluded: in one case they employed a private-mixed dental sealant delivery system; in two cases the territorial areas under their responsibility were inaccessible. Tooth brushing coverage with fluoride toothpaste in this area was reported to be 98.7-100%.

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This study was a single-blind cluster-randomized control trial and parallel group study. The clusters were CUPs which included groups of dental nurses who administered school sealant programs. The cluster trial was designed because of the intention of accepting the evidence from the dental team for CUP-level feedback to promote the application of sealant effectiveness (details in the intervention).

Eligible clusters were CUPs which provided a school sealant program for primary schoolchildren. All dental nurses who implemented this program in each CUP were included. All children were sealed according to sealant application criteria; sound first molar with deep pit and fissure and cooperative children. The sealant material used in this study was Concise® (3M). A school sealant program was delivered into two types of setting: school-based in temporary clinics using mobile dental equipment for one or two days; and permanent hospital-based sealant services based on the referral of children after being screened for sealant need at their school. While in general, moisture control and light was better in hospital-based services, school-based services increased access to sealant services.

The intervention was designed based on the model and strategy suggested by Hysong *et al.* (2006) and Hysong (2009). The model of actionable feedback identifies timeliness, individualization, punitiveness and customizability as features affecting performance. The strategies of specific suggestion for improvement and delivery the writing feedback were included. At the beginning of the study, a preliminary workshop was conducted at which the objectives of the program were set out and the design for the system based on the above model and strategy was customized. The school sealant program was conducted in the usual way after the preliminary workshop. Half-yearly audit and feedback was proposed by dental nurses based on the nature of sealant retention and caries outcome. From the point of dental nurses, the CUP-level data feedback was more comfortable for them than individual-level feedback. Non-punitive feedback and tailor-made performance improvement was initiated by presenting the most common failures with pictures, and a session of sharing experience and discussion was requested.

The data from the first audit were analyzed and the feedback phase was conducted in two ways. The first method involved conducting workshops among the dental nurses in the intervention group. The data on sealant retention failures and caries were classified into six scenarios and the dental nurses discussed and identified the common causes and the ways to solve of these scenarios. The second method was the presentation of quantitative data which included the sealant retention rate, and the rate of caries on the surface of sealed teeth. All data were presented at both provincial level and cluster level; therefore, the providers in each cluster were able to compare their results with the overall result. The second set of feedback data were given confidentially to each cluster during the workshop in a sealed envelope.

The control group received the same examination procedure but no data were given back to them. After the feedback phase, the sealant delivery was conducted again as usual. The sealed children then were examined for evaluation of the intervention program.

The two indicators of service quality of school dental sealant were sealant retention and the presence of caries, both assessed six months after sealing in the different groups of children before (for baseline and audit information) and after intervention (to evaluate the intervention).

Sealant retention was classified as either *completely retained, partially retained or total loss of sealant retention* using previously published criteria (Tianviwat *et al.*, 2008). The detection of caries was discoloration of the occlusal surface and sticking with gentle probing (Tianviwat *et al.*, 2008). The Kappa values for intra-examiner agreements were 0.75-0.8 for sealant retention and 0.80-0.85 for caries detection. The inter-examiner agreements were 0.75 for sealant retention and 0.82 for caries. There were two external examiners who, unlike the data analyst and dental nurses, were not blind to the intervention because they were responsible for the feedback phase; conducting the common failure workshop and providing the feedback data. The dental nurses in the control group did not know that the intervention group received the feedback data. For ethical reasons, the researchers informed all participants that they would be evaluated on their sealant performance.

Baseline variables were collected by the dental nurses to establish tooth and child characteristics and noted in the treatment record forms.

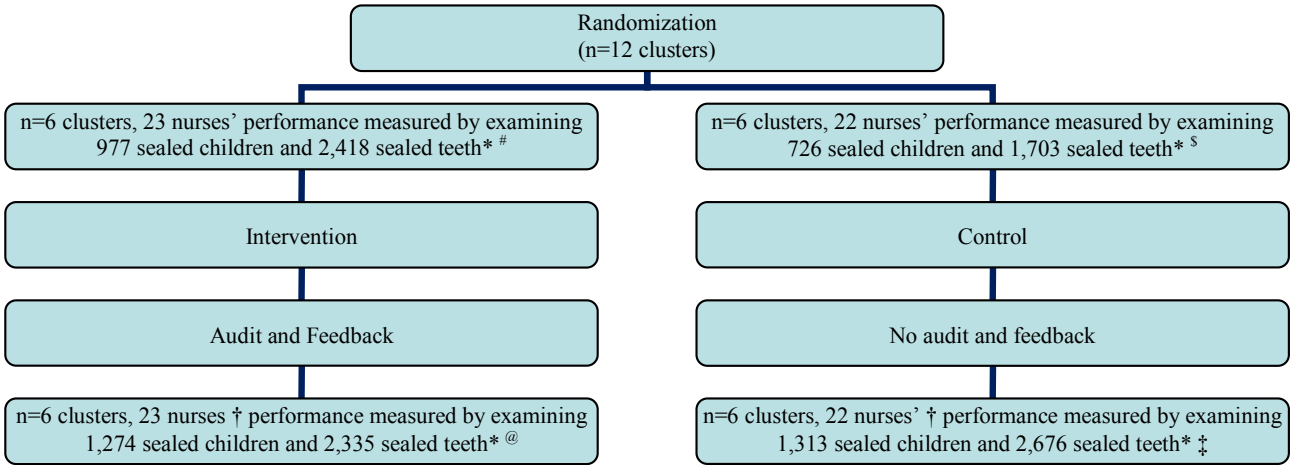
It was apparent from the preliminary workshop that the dental nurses wanted to know the shortcomings in their performance, so the researchers designed the study to include all sealant cases handled by the selected CUPs. Therefore, the total numbers of school children on which the study was based were 1,703 at the beginning of the study (726 control, 977 intervention) which increased to 2,587 at the end (1,313 control, 1,274 intervention). The increase was because in the first semester children were screened then treated whereas in the second semester more time was spent treating children as they had been screened in the earlier semester. The number of sealed children depended on the size of the CUP; more children in the larger CUPs. Therefore, the manpower (dental nurses) to 1,000 children ratio was used as the controlling variable. The sample size was adequate based on the guidelines suggested for cluster randomized trials by Cosby *et al.* (2003) and calculated using the following values from previous study (Tianviwat *et al.,* 2008; Obsuwan *et al.* 2008): intraclass correlation=0.015, power=80%, outcome difference between intervention and control groups=15% and alpha=0.05. The outcome difference between intervention and control groups approximate from the previous studies in a similar setting; the first study (Tianviwat *et al.*, 2008) presented the effectiveness of a school sealant program with the refresher course and the latter study (Obsuwan *et al.,* 2008) presented the routine school sealant program without any intervention. The different effectiveness between the two reports was 10% (55% vs 45%). We expected higher effectiveness in this study than in the previous studies; therefore we used 15% difference in effectiveness. The number of clusters was 6 per group. The estimated total number of children required was 769 in each of the intervention and control clusters.

The study included 12 CUPs; 6 intervention clusters with 23 dental nurses and 6 control clusters with 22 dental nurses. All children who were sealed were included. Simple randomization (by the first author) of CUPs was applied using a computer-generated list of random numbers. Allocation concealment was by writing the CUP's name on the papers then folding them before allocation by a research assistant after completing all baseline examinations.

$$\text{Logit}\ (p(Y_{ijk} = 1)) = \beta_0 + \beta_{1\ldots n}x_{nijk} + \beta_{1\ldots m}x_{mjk} + \beta_{1\ldots l}x_{lk} + \beta_p \text{group*time}_{mjk} + (v_{ok} + u_{0jk} + e_{0ijk})$$

With Y_{ijk} the outcome for tooth i (i.e. sealant retention or caries on sealed surface) in child j and CUP k;
β_0 the intercept
x_{nijk} = variables *1* to *n* at tooth level *i.e. jaw, oral hygiene;*
x_{mjk} = variables *1* to *m* at child level i.e. time, setting, gender, caries experience*;*
x_{lk} = variables *1* to *l* at CUP level i.e. manpower, sealant coverage, group;
$B_{1\ldots n}$ = effect of $X_{1\ldots n}$ variables at tooth level;
$B_{1\ldots m}$ = effect of $X_{1\ldots m}$ variables at child level;
$B_{1\ldots l}$ = effect of $X_{1\ldots l}$ variables at CUP level;
B_p = effect of interaction term between group and time (only in the sealant retention model)
v_{ok} the random intercept for the CUP;
u_{0jk} the random intercept for the child and e_{0ijk} the residuals.

Figure 1. *Random effect logistic regression with random intercept for the child level and the CUP level including group of intervention*



* Different group of children; # Participation rate was 95.4 % among 1,024 sealed children; $ Participation rate was 95.7 % among 759 sealed children; † No loss to follow-up; @ Participation rate was 95.9 % among 1,329 sealed children; ‡ Participation rate was 96.1% among 1,366 sealed children

Figure 2. *Flow diagram of the procedure*

Data were analysed using the R program, v.3.2.1 (R Development Core Team, 2015). Multi-level modeling (Figure 1) was used for hierarchical structures and clustered data (Campbell *et al.,* 2000). Sealant retention and caries on the sealed surface of teeth were the dependent variables, which were lower-level nested. In data analysis, sealant retention was divided into two categories; complete retention and loss of sealant (combined partial and total loss). Adjustment for cluster effects was conducted by including children and CUP as the higher levels in the analysis. Random effects were represented in the intercept variances at child level and CUP level. The variables of group (control or intervention), time of study (baseline or end), service settings (mobile or hospital), and children's and tooth characteristics were investigated. The analysis of crude and adjusted odds ratios for interaction model was done based on the method suggested by Twisk (2006). No important change of method occurred after trial commencement and no interim analysis was performed. The research protocol was approved by the Ethics Committee of the Faculty of Dentistry, Prince of Songkla University (No.0521.1.03/211). This study was registered in the Thai Clinical Trials Registry as TCTR20120000024.

Results

This study was conducted between March 2009 and March 2012. The flow diagram of the procedure adopted is shown in Figure 2. All 45 dental nurses enrolled in the study and participated for the whole period of the study with no non-compliance.

The average number of sealed teeth per child was 2.3 in the control group and 2.5 in the intervention group. There were no unintended effects occurring in any group.

Table 1 presents the characteristics of the children and of the sealed teeth at the beginning and end of the two periods assessed in both the control and intervention groups. Before intervention, there was no significant difference in the data related to the setting in which the children's teeth were sealed, gender or caries outcome on sealed surface between two groups. However, there were significantly more upper teeth sealed, poorer oral hygiene and higher caries in primary teeth in the intervention group than in the control group. In the data relating to the post-intervention period, the same patterns were identified and in addition it was found that more teeth were sealed in a school setting and there were more boys in the intervention group than in the control group.

Table 1. Baseline characteristics, sealant retention and caries on sealed surface of examined children and teeth before and after intervention

Characteristics	*Before intervention (%)*			*After intervention (%)*		
	Control	*Intervention*	*p-value*	*Control*	*Intervention*	*p-value* [d]
Tooth level						
Tooth position [a]						
Upper	566 (33.2)	1164 (48.1)		487 (18.2)	1081 (46.3)	
Lower	1137 (66.8)	1254 (51.9)	<0.001	2189 (81.8)	1254 (53.7)	<0.001
Oral Hygiene [a]						
Poor	817 (48.0)	1482 (61.3)		1551 (58.0)	1675 (71.7)	
Good	886 (52.0)	936 (38.7)	<0.001	1125 (42.0)	660 (28.3)	<0.001
Sealant Retention [a, e]						
Loss	800 (47.0)	1623 (67.1)		1226 (45.8)	815 (34.9)	
Complete	903 (53.0)	795 (32.9)	<0.001	1450 (54.2)	1520 (65.1)	<0.001
Caries on sealed surface [a, e]						
Yes	73 (4.3)	99 (4.1)		158 (5.9)	106 (4.5)	
No	1630 (95.7)	2319 (95.9)	0.761	2518 (94.1)	2229 (95.5)	0.031
Child level						
Setting [b]						
School	457 (62.9)	631 (64.6)		957 (72.9)	1040 (81.6)	
Hospital	269 (37.1)	346 (35.4)	0.487	356 (27.1)	234 (18.4)	<0.001
Gender [b]						
Boy	386 (53.2)	511 (52.3)		629 (47.9)	660 (51.8)	
Girl	340 (46.8)	466 (47.7)	0.724	684 (52.1)	614 (48.2)	0.047
Caries experience in primary teeth [b]						
Low (dmft≤9)	408 (56.2)	498 (51.0)		979 (74.6)	654 (51.3)	
High (dmft>9)	318 (43.8)	479 (49.0)	<0.001	334 (25.4)	620 (48.7)	<0.001
CUP level						
Manpower per 1,000 children [c]	Control (range) 0.8 - 2.1		Intervention (range) 0.4 – 2.2			0.83
Sealant coverage (%) [c]	Control (range) 12.8 - 20.0		Intervention (range) 11.3 - 43.6			0.77

[a] Tooth characteristics n=4121 teeth at baseline (1,703 control, 2,418 intervention) and n=5,011 teeth at the end (2,676 for control and 2,335 for intervention); [b] Children's characteristics; n=1,703 children at baseline (726 control, 977 intervention) and n=2,587 children at the end (1,313 control, 1,274 intervention); [c] District's characteristics; n=12; [d] Chi-square test for tooth characteristics and children characteristics, independent t-test for district characteristics; [e] Main outcomes, In the analysis, sealant retention divided into two categories; complete retention and loss of sealant (combined partially and totally loss)

In the pre-intervention period, the control group had a higher sealant retention rate than the intervention group whereas after intervention the intervention group had a higher rate of sealant retention. Caries on sealed surface showed no difference between the two groups in the pre-intervention period, whereas in the post intervention period there were less caries in the intervention group than in the control group. There was no difference of manpower and sealant coverage between the two groups.

Table 2 shows the odds ratio (OR), 95% confidence interval (CI) and p-values from multi-level logistic regression with sealant retention as the dependent variable and controlling for the effect of group by time. A significant interaction between time and group was tested in sealant retention model ($p<0.001$). So, the effect on the the group is significantly different for before and after implementation. The estimated adjusted OR in the pre-intervention period was less than 1 indicating a lower rate of complete retention in the intervention group than in the control group. However, it was not significant. In contrast, the odds for complete retention in the post intervention period was higher among the intervention group, 1.99 times that of the control group.

The results from multi-level logistic regression with caries on sealed surfaces as the dependent variable are presented in Table 3. No significant effect on caries on sealed surfaces resulting from the audit and feedback strategy was evident.

Discussion

Based on the study's findings, the audit and feedback system had a strong effect on sealant retention. However, this strategy had no observable effect on the incidence of caries among vulnerable children.

The success of this study was mainly due to the design of the system, which was an intensive tailor-made audit and feedback system incorporating specific suggestions for improvements in performance (Hysong *et al.,* 2009).The system was designed by the dental nurses who suggested the type of feedback information to be incorporated and made use of data relating to common failure discussed in the initial workshop. The emphasis was on solving problems which were found to be very different from cluster to cluster and this clearly showed how the dental nurses had used the feedback data to improve their performance and changed their attitude toward dental service quality (Tianviwat *et al.,* 2015), i.e. tooth and case selection and awareness toward sealing procedure. Regarding Hysong *et al.* (2009), low performers relied on facility-level report. However, in this study, the CUP level feedback data was merged with intensive feedback delivery and provided the good result. According to Ivers *et al.* (2012), the low baseline effectiveness of sealant retention in the intervention group might affect the success of the program. However, adjusted OR of the baseline effectiveness was not significant.

Table 2. Crude and adjusted odds ratios, 95% confidence interval and p-values for the effect of intervention on sealant retention 'before and after' intervention

Variables (reference)	*OR*	*95%CI*	*p-value*
Crude analysis			
Before audit and feedback			
Intervention (control)	0.43	0.31, 0.56	<0.001
After audit and feedback			
Intervention (control)	1.58	1.46, 1.69	<0.001
Adjusted analysis			
Fixed effect			
Intercept	0.67	-0.41, 1.75	0.46
Intervention vs control			
Before audit and feedback			
Intervention (control)	0.47	-0.31, 1.26	0.099
After audit and feedback			
Intervention (control)	1.99	1.21, 2.78	<0.001
Confounding factors			
Girl (boy)	1.02	0.93, 1.11	0.64
Lower (upper)	1.06	0.95, 1.16	0.29
Good (poor hygiene)	0.84	0.74, 0.94	<0.001
Hospital (mobile setting)	0.91	0.73, 1.08	0.26
Caries experience (low)	1.03	0.94, 1.13	0.50
Manpower:1000 children	3.08	2.08, 4.08	0.06
Sealant coverage (retained)	0.96	0.91, 1.01	0.16
Random effect (standard deviation)	Level 1 (tooth) = 1 Level 2 (children) = 0.38 Level 3 (CUP) = 0.32		

Reference level for sealant retention = loss of sealant retention

Table 3. Crude and adjusted odds ratios, 95% confidence interval and p-values for the effect of intervention on caries on sealed surfaces

Variables (reference)	*OR*	*95%CI*	*p-value*
Crude analysis	1.20	1.00, 1.40	0.061
Adjusted analysis[a]			
Fixed effect			
Intercept :	39.80	38.77, 40.88	<0.001
Intervention (control)	1.37	0.63, 2.10	0.43
Confounding factors			
Girl (boy)	0.88	0.69, 1.07	0.20
Lower (upper)	0.59	0.36, 0.83	<0.001
Good (poor hygiene)	0.89	0.68, 1.10	0.28
Hospital (mobile setting)	0.82	0.46, 1.17	0.27
Caries experience (low)	0.70	0.50, 0.91	<0.001
Manpower:1000 children	2.26	1.24, 3.27	0.15
Sealant coverage (retained)	0.97	0.92, 1.01	0.19
Random effect (standard deviation)	Level 1 (tooth) = 1 Level 2 (children) = 0.71 Level 3 (CUP) = 0.52		

[a] No interaction in the model
Reference level for caries on sealed surface = caries

There were significant differences of baseline data between intervention and control groups especially in the main outcome, sealant retention. This difference might have arisen from the small number of clusters (6 per group). The simple random allocation was performed using lottery technique with well conducted concealment. The other differences of teeth and children characteristics depended on whether teeth or children were meeting sealant criteria. Since this study was done under the routine environment of school sealant program, the sampling design did not attempt to balance child and tooth characteristics, but we adjusted for these variables in the analysis.

Even though there was a statistically significant difference in the incidence of caries between the intervention and control groups, there was no observable impact from the audit and feedback system on the rate of caries on sealed surfaces. The explanation might lie in the short follow-up time, the sensitivity of the diagnosis of caries or the nature of caries as a multi-factorial disease. Caries progress over a long period and a six month follow up interval is sometimes suggested for a clinical routine check-up for the purpose of prevention. However, to fully assess the impact of the intervention on the control of caries a longer period would be needed. In the case of a short-term evaluation, a more sensitive caries diagnosis test than that used in this study might be more appropriate, e.g. the International Caries Detection and Assessment System-II (ICDAS-II). The weakness of the study for caries model was not including some confounding variables, e.g. individual fluoride use, sugar consumption.

However, in all probability the most important explanation for the intervention not having a significant effect on the rate of caries is that they are caused by many different factors and the application of sealant is only one factor in their prevention. Once the sealant is lost, the effect of preventing caries also disappears. Teeth would be prone to caries as a result of other risk factors such as poor oral hygiene, cariogenic food or inadequate fluoride use. The possible explanation for improvement of sealant effectiveness might be from the Hawthorne effect. The dental nurses tended to perform harder and better because they knew that they participated in the study. However, all of the CUPs were informed before implementation, so this effect should have been balanced in the two groups.

Even though the study was designed as a randomized controlled trial, there was a possibility of bias being introduced into the results by the lower pre-intervention level of sealant retention in the intervention group than in the control group due to the limited number of clusters. However, the interaction between group and time was noted and controlled for in the multi-level regression analysis. The blind design of this study sought to eliminate some possible sources of bias but this may not have been effective in entirely eliminating an effect from the dental nurses in the control clusters becoming aware of the operation of the audit and feedback system. Since service-wide dental staff met monthly in Songkhla they might have come to know that the audit and feedback study was being conducted in some areas. However, the most important aspect of the study was the feedback system which was tailored-made and the feedback regarding the retention of sealant and the incidence of caries was confidential to the intervention areas, thus reducing this aspect of the study as a source of bias. There was no blinding of the examiners in this study because the researchers were deeply involved in deriving the audit data and designing the feedback workshop scenarios.

Other limitations of this study were that there were a limited number of clusters allocated to the intervention and control groups, and the number of sealed teeth and the number of children whose teeth were sealed varied between clusters. Strengths of the study were the intervention design and the statistical analysis.

Conclusion

The study clearly shows that the intensive audit and feedback system improved the quality of the dental service in rural areas to a level similar to that previously reported in urban areas (Hintao *et al.,* 2013). However, there was no significant impact from the intervention on the level of dental caries on the sealed surfaces. Sealant only decreased tooth morphology susceptibility to caries. There is therefore, a need for a significant improvement in and promotion of all programs related to oral health and the prevention of caries.

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