Community Dent Oral Epidemiol 2004; 32: 159–65

COMMUNITY DENTISTRY AND ORAL EPIDEMIOLOGY

Relationship between area deprivation and the anticaries benefit of an oral health programme providing free fluoride toothpaste to young children

R. P. Ellwood[1], G. M. Davies[2], H. V. Worthington[3], A. S. Blinkhorn[3], G. O. Taylor[4] and R. M. Davies[1]

[1]Dental Health Unit, Manchester, [2]Central Manchester Primary Care Trust, Manchester, [3]University of Manchester Dental School, Manchester, UK, and [4]Tameside and Glossop Primary Care Trust, Manchester, UK

Ellwood RP, Davies GM, Worthington HV, Blinkhorn AS, Taylor GO, Davies RM. Relationship between area deprivation and the anticaries benefit of an oral health programme providing free fluoride toothpaste to young children. Community Dent Oral Epidemiol 2004; 32: 159–65.

Abstract – *Objective:* To determine the effectiveness of providing free toothpaste containing either 1450 or 440 ppm F on caries experience in 5-year-old children living in areas with different levels of material deprivation. *Design:* Five-year, examiner-blind, randomized, controlled, parallel-group, clinical trial. Children were randomly assigned to three groups. *Setting:* Health Districts in the north-west of England with high levels of dental caries. Clinical examinations were performed in schools during the period October 1999 to April 2000 when the children were 5–6 years old. *Participants:* Children from 3-month birth cohorts resident in nine, nonfluoridated health districts. *Interventions:* Toothpaste containing either 440 or 1450 ppm F and dental health literature posted at 3-month intervals and toothbrush provided annually from the age of 1–5$\frac{1}{2}$ years. Comparison group received no intervention. *Main outcome measures:* Mean dmft and proportion of participants with dmft > 0, dmft $\geq$ 4, upper primary incisor caries and extraction of one or more primary teeth. Outcomes tabulated for quartiles of participants based on the distribution of the Townsend index of material deprivation. *Results:* A total of 3467 children were included in the final data analysis. The Townsend index was found to be useful in identifying groups of children with increased caries risk. Overall, participants in the programme using the high-fluoride toothpaste had significantly ($P < 0.002$) less caries than the comparison group with similar absolute reductions in mean dmft for the most- and least-deprived groups. Relative to the comparison group the association between deprivation and dental caries was changed so that in the most-deprived quartile those using the low-fluoride toothpaste tended to have less dental caries than the comparison group whereas in the least deprived they tended to have more. This difference in the association (slope) was statistically significant ($P < 0.05$). Provision of both low- and high-fluoride toothpaste appeared to reduce the risk of extractions for participants in the most-deprived quartile ($P < 0.05$). *Conclusion:* The relative benefits of the programmes supplying the two toothpastes considered in this study are different depending on the deprivation status of the participants. For the most-deprived groups postal provision of either a low- or high-fluoride toothpaste provides similar levels of benefit. In the less deprived groups only provision of the high-fluoride

Key words: caries; fluoride toothpaste; inequalities; material deprivation; preschool children

Dr R. P. Ellwood, Dental Health Unit, Manchester Science Park, Lloyd Street North, Manchester, M15 6SH, UK Tel: +44-161-232-4705 Fax: +44-161-232-4700 e-mail: roger.ellwood@man.ac.uk

Submitted 17 April 2003;
accepted 6 October 2003

toothpaste provided a benefit. The absolute caries reduction seen for provision of the high-fluoride toothpaste was not related to the deprivation status and hence the programme did not reduce deprivation-related health inequalities. Targeting the programme using the methods employed in this study is unlikely to improve the effectiveness of the programme.

In the United Kingdom, water fluoridation has not been implemented widely and alternative methods of providing the benefits of fluoride to high caries risk populations must be investigated. We have previously reported the results of a dental health programme that posted free fluoride toothpaste to children, initially aged 12 months, living in non-fluoridated districts in the north-west of England with high levels of dental caries (1). It was concluded that the sustained delivery of toothpaste containing 1450 ppm F at 3-month intervals provided a significant 16% reduction in caries experience at 5–6 years of age when compared with a comparison group which received no intervention. In contrast, the provision of a low-fluoride toothpaste (440 ppm F) did not provide an overall clinical benefit (2).

The recommendation to supply a high-fluoride toothpaste to young children is controversial and it is pertinent to investigate the impact of such a postal programme on children from different backgrounds. The children who participated in this programme were from areas with different levels of social deprivation and there is a strong relationship between area measures of material deprivation and caries levels (3, 4). Therefore, the data were further analysed to determine the relative benefit of the postal programme supplying either high- or low-fluoride toothpastes in relatively deprived and nondeprived populations. It was anticipated that children in the most-deprived areas would benefit more from the high-fluoride toothpaste whereas children in the least-deprived areas might derive adequate protection from the low-fluoride toothpaste.

The aim of this study was to determine the effectiveness of providing free toothpaste containing either 1450 and 440 ppm F on caries experience in 5-year-old children living in areas with different levels of material deprivation.

Method

This study was conducted in nine health districts in the north-west of England with fluoride in the drinking water at <0.1 ppm. These districts were initially selected because they had high levels of dental caries in children aged 5 years. A detailed description of the study method has been reported previously (2).

The study statistician randomly allocated a birth cohort of 7422 children from nine health districts to one of three groups. The flow of participants through each stage of the trial is shown in Fig. 1. Each child received either a 1450- or a 440-ppm F toothpaste from 12 months of age or had no intervention. At the age of 12 months, children in the two groups who had been randomly allocated to receive free fluoride toothpaste were contacted to obtain informed consent for participation in the study. Of the 4960 children in these two groups, 641 withheld consent to take part. Consent for the children in the comparison group to be examined was obtained when the children were 5–6 years old.

Ethical approval for the study was obtained from the Local Research Ethics Committees of all districts involved in the study and with the approval of the relevant Instititutional and Medical Authorities. In the UK children's toothpastes containing low levels of fluoride (<600 ppm) are available but it is common for young children to use a family toothpaste containing 1450 ppm F. Literature provided to the children with the 3-month deliveries of toothpaste advised the parents to brush the child's teeth morning and evening with a pea-sized amount of toothpaste and to spit the toothpaste out after brushing. It also advised against using fluoride tablets during the course of the study unless advised to do so by their own dentist.

During the course of the study, 1432 children in the three groups moved from the study area. Five children withdrew from the 1450 ppm F group, one following the advice of their dentist, three because of concerns about fluorosis and one because of allergy to toothpaste. A total of 3731 participants were examined and completed the study. At the outset it was estimated that a sample size of 1250 would have 95% power to detect a difference in means of 15% between three possible pairwise comparisons with 0.05 two-sided significance level

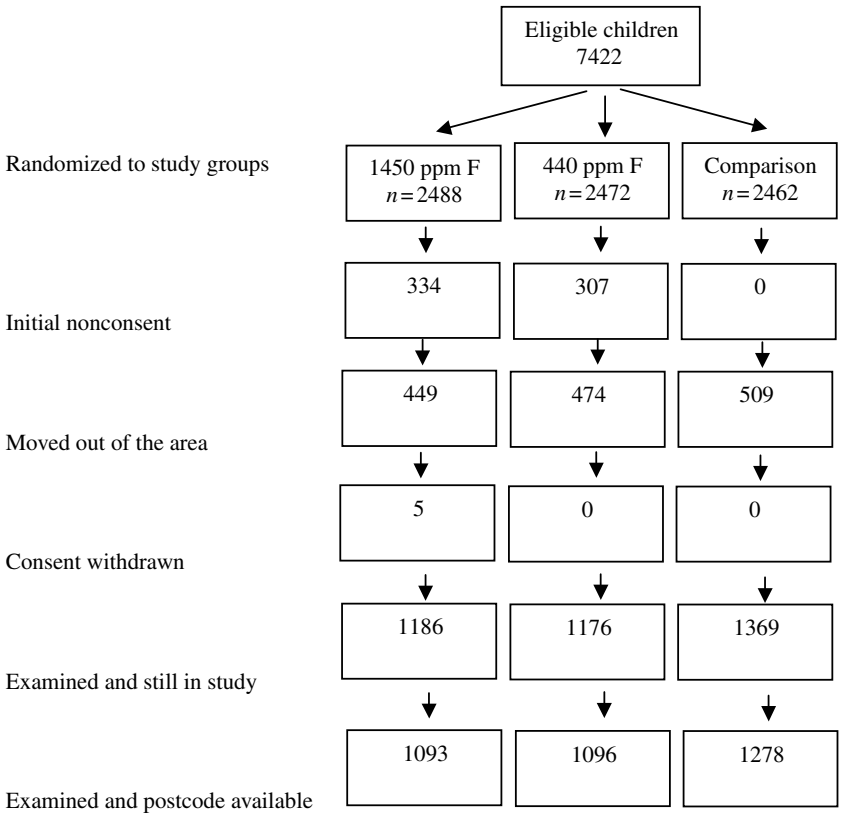

Fig. 1. Flow of participants between each stage of the study.

and applying a Bonferroni correction (assuming a coefficient of variation of unity).

Those allocated to the toothpaste groups received an 'off the shelf' tube of toothpaste (without overwrapping or repackaging) every 12 weeks until they were $5\frac{1}{2}$ years old. A toothbrush was also provided annually for those in the toothpaste groups. Children were examined when they were 5–6 years old during the period October 1999 to April 2000. The children were examined for caries at the dentinal level using the standards set by the British Association for the Study of Community Dentistry (BASCD) (5). All 10 dental examiners involved in the study completed the BASCD training programme prior to commencement of the study and attained kappa values of >0.75 for surface scores compared with a gold standard examiner.

Townsend scores were calculated for electoral wards using the 1991 census data. The Townsend index uses four weighted census variables describing unemployment, household overcrowding, car ownership and numbers in rented accommodation and an index is produced with increasing scores representing increasing levels of material deprivation (6). Using the participants' postcode at entry into the study the Townsend score for the electoral ward of residence of the subject was added to the study database. The participants were divided into quartiles using the frequency distribution of the Townsend area scores for all participants included in the final data analysis.

For each quartile several outcomes were calculated and tabulated for each of the three study groups; the mean dmft (primary outcome) and the percentages of participants with dmft > 0, dmft $\geq$ 4, dmft > 0 on the upper primary incisors and one or more teeth extracted because of caries. Within each of these quartiles differences between the three group means were compared using an anova and applying a Bonferroni correction to the *P*-value for paired comparisons. Differences in the association between mean dmft and the Townsend group quartile for the three study groups were tested using a linear regression model with interaction terms representing the difference in slope between the groups. Differences between proportions were compared using a chi-square test. The overall α level of significance was set at 0.05.

Results

Of the 3731 participants who completed the study and were examined, postcode matches were available for a total 3467 (93%). In this study, the highest (most deprived) Townsend ward score

Table 1. Mean (SD), minimum and maximum electoral ward Townsend scores for participants completing the study in each of the nine districts

District	Participants (*n*)	Townsend score		
		Minimum	Maximum	Mean (SD)
Bolton	406	−4.58	10.47	2.34 (3.80)
Tameside	384	−3.64	8.98	2.24 (2.24)
Oldham	428	−3.32	10.67	3.67 (4.25)
Salford	230	−4.15	10.97	4.39 (3.36)
Wigan	460	−2.80	7.77	1.34 (2.43)
Burnley	371	−6.17	9.47	1.75 (3.49)
Blackburn	519	−6.42	10.59	2.25 (4.38)
Skelmersdale	173	−4.51	7.62	1.05 (4.01)
South Sefton	496	−4.57	9.42	1.15 (3.83)

for the participants was 10.97 and the lowest −6.42. The participants in each of the nine districts were residents of electoral wards representing a wide range of Townsend scores (Table 1). The mean Townsend scores for the four quartiles of the subject distribution were −2.2, 0.47, 3.1 and 7.4 (Table 2). The mean Townsend score for all participants completing the study was 2.19 ± 3.74. There was a strong trend for the final mean dmft to increase from the least to the most deprived for all study groups. The mean dmft for quartiles 1 (least deprived) to 4 (most deprived) were 1.8, 2.2, 2.7 and 2.9, respectively. The differences between each of the four quartiles were statistically significant ($P < 0.05$), the only exception being between the two most-deprived quartiles.

The mean dmft for participants in the programme using the low-fluoride toothpaste in the least-deprived quartile was 2.2 compared with 1.4 for those using the high-fluoride toothpaste. This difference of 36% was statistically significant ($P < 0.05$). Participants in this quartile using the low-fluoride toothpaste (dmft 2.2) also had more caries than the comparison group (dmft 1.9) but the difference was not statistically significant ($P > 0.05$). In the most-deprived quartile participants receiving both the low- and high-fluoride toothpastes had less dental caries (2.9 versus 2.7) than the comparison group (3.2) but the differences were not statistically significant.

The relationship between the Townsend quartile and the mean dmft is illustrated in Fig. 2. It can be seen that the slope of the association between the Townsend quartile and dmft for the 1450 ppm F and comparison group is similar ($P > 0.05$) with the comparison group having more caries (0.4 dmft) than the 1450 ppm F for all four quartiles ($P < 0.002$). It can also be seen that the association between dmft and the quartiles for the 440 ppm F group was different from the other two postal toothpaste groups. Subjects in the least-deprived quartile using the 440 ppm F paste tended to have more caries than the other two groups, whereas in the two most-deprived quartiles participants using the 440-ppm F paste had numerically less caries than the comparison group. The difference in slope between dmft and Townsend quartile was statistically significant ($P = 0.04$).

The percentages of participants with dmft > 0 or dmft of $\geq$4 increased from the least to most-deprived quartiles. In the least-deprived quartile only 16% of participants receiving high-fluoride toothpaste had a dmft $\geq$4 compared with 27% of those using low fluoride. In the most-deprived quartile the prevalences in the three study groups were similar. Overall when compared with the comparison group, provision of low-fluoride toothpaste increased caries prevalence for the least deprived, whereas in the most-deprived quartile provision of either low- or high-fluoride toothpaste tended to reduce caries.

The number of participants with caries involving one or more of the upper primary incisors ranged from 6% for participants receiving the high-fluoride toothpastes in the least-deprived quartile to 18% for participants in the comparison group in the most-deprived quartile. The provision of low- or high-fluoride toothpaste did not have a significant impact on the prevalence of incisor caries.

Provision of both low- and high-fluoride toothpastes reduced the number of participants with experience of extraction from 21 to 14% in the most-deprived quartile ($P = 0.03$). For the comparison group, the percentages of children with extracted teeth increased from 10% in the least- to 21% in the most-deprived quartile.

Table 2. Mean dmft and percentages of participants dmft > 0, dmft ≥ 4, dmft > 0 in deciduous upper incisors and with deciduous extraction for quartiles of the subject distribution of the Townsend index

	Quartile of Townsend score											
	Quartile 1 (least deprived)			Quartile 2			Quartile 3			Quartile 4 (most deprived)		
Townsend mean (SD):	−2.22 (1.20)			0.47 (0.60)			3.05 (0.79)			7.40 (1.85)		
	1450 ppm F	440 ppm F	Comparison	1450 ppm F	440 ppm F	Comparison	1450 ppm F	440 ppm F	Comparison	1450 ppm F	440 ppm F	Comparison
n	280	251	328	281	302	283	268	276	332	264	267	335
Mean dmft (SD)	1.4 (2.5)	2.2 (3.0)	1.9 (2.9)*	2.0 (2.9)	2.3 (3.0)	2.3 (2.9)	2.6 (3.3)	2.6 (3.1)	2.8 (3.1)	2.7 (3.0)	2.9 (3.6)	3.2 (3.4)
dmft > 0 (*n*; %)	112 (40)	129 (51)	145 (44)*	129 (46)	175 (58)	159 (56)*	151 (56)	168 (61)	209 (63)	161 (61)	157 (59)	228 (68)*
dmft ≥ 4 (*n*; %)	46 (16)	68 (27)	73 (22)*	67 (24)	83 (28)	82 (29)	86 (32)	85 (31)	119 (36)	92 (35)	94 (35)	130 (39)
Caries deciduous upper incisors (*n*; %)	16 (6)	24 (10)	30 (9)	28 (10)	28 (9)	26 (9)	29 (11)	27 (10)	39 (12)	45 (17)	44 (17)	61 (18)
Extracted teeth (*n*; %)	25 (9)	25 (10)	34 (10)	31 (11)	42 (14)	45 (16)	39 (15)	46 (17)	69 (21)	37 (14)	38 (14)	70 (21)*

*Significant differences between the three groups within the quartile.

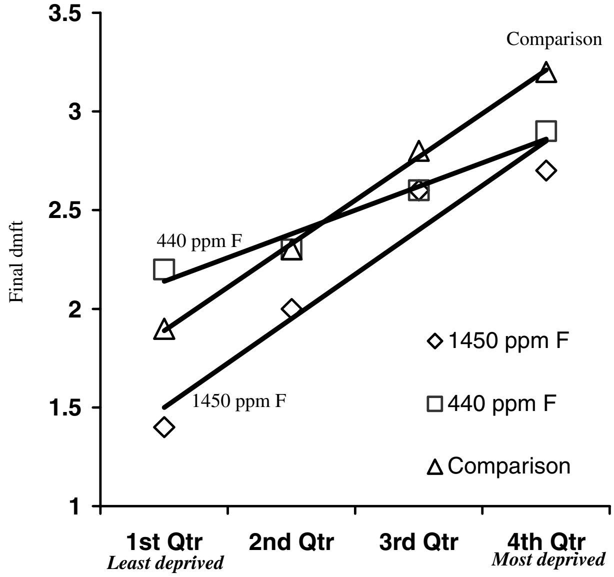

Fig. 2. Trend lines illustrating the relationship between dmft and deprivation quartile for the three study groups.

Discussion

The overall aim of this randomized controlled clinical trial was to assess whether the regular provision of free fluoride toothpaste and leaflets, encouraging twice daily brushing with a pea-sized amount of toothpaste, could reduce dental caries in young children from nonfluoridated areas in the north-west of England. The study was not designed to compare the anticaries efficacy of low- and high-fluoride toothpastes but rather evaluate the effect of their provision in a public health programme. Children in the comparison group would have been able to purchase the toothpastes, or similar, to those provided to the two test groups.

The mean Townsend ward score for participants completing this study was 2.2 compared with a mean of 0.0 (3.52) and minimum and maximum of −6.8 and 15.5 for the 9509 electoral wards in England and Wales. The participants in the study were, therefore, from areas with a wide range of deprivation scores similar in distribution to England and Wales. The relationship between material deprivation and dental caries is complex and is influenced by behavioural and physiological factors in addition to locality factors such as the relationship between neighbourhoods (7, 8). A significant problem with epidemiological studies using these methods is the bias that may occur when an association at an aggregate level (such as area) is identified that may not represent that existing at an individual level (ecological fallacy).

In this study rather than use the area-based approach to understand differences that occur between localities it was used to assess the likely impact of targeting an intervention to deprived communities using these methods. The Townsend index was found to be useful in identifying populations with high caries risk with a dmft in the least-deprived quartile of 1.8 compared with 2.9 in the most-deprived quartile, a difference of 38%. However, as with all approaches of this type there were many participants in the 'low' risk, least-deprived group with high levels of caries.

It was expected at the outset of this study that children in the most-deprived areas would benefit more from the high-fluoride toothpaste whereas children in the least-deprived areas might derive adequate protection from the low-fluoride toothpaste. In all four quartiles, the provision of high-fluoride toothpaste resulted in greater caries reductions when compared with the comparison group. For both the most- and least-deprived quartiles, the absolute reduction was 0.5 dmft representing percentage reductions of 16 and 26 compared with the comparison groups, respectively. It would appear, therefore, that the provision of fluoride toothpaste to the whole population does not significantly reduce health inequalities between children from the most- and least-deprived areas within that population. The mean dmft in the comparison group for the two least-deprived quartiles was 2.1 compared with 3.0 for the two most deprived, a difference of 30%. Provision of high-fluoride toothpaste to the children in these two most-deprived quartiles might be expected to reduce dmft to approximately 2.6 teeth, a difference of only 19% from the comparison group mean of the two least-deprived quartiles. Overall, these results suggest that the efficiency of the programme using the high-fluoride toothpaste is unlikely to be improved by targeting resources at the least-deprived quartile as the absolute reduction in caries was similar for all four quartiles.

Overall, children in this study using the low-fluoride toothpaste had similar levels of caries to the comparison group. However, the provision of low-fluoride toothpaste in this programme appeared to change the association between deprivation and caries. There was a tendency for participants in the least-deprived quartile using the low-fluoride toothpaste to have slightly more caries than the comparison group, whereas in the most-deprived quartile they tended to have less caries. This significantly reduced the slope of the association between caries and the deprivation quartile by increasing the caries prevalence in the least-deprived quartiles and reducing it in the most deprived. These results suggest that a postal programme using a low-fluoride toothpaste may be as effective as that using a high-fluoride toothpaste in the most-deprived quartile and provide the optimum compromise between benefit and risk. However, differences were not statistically significant between the three groups in this quartile and further work is required to clarify this outcome.

The efficacy of this programme is dependent, amongst other factors, on the type of toothpaste used and the relative success of promoting positive oral health behaviours. It could be argued that children in the least-deprived group were already practising positive oral health behaviours, such as tooth brushing, and encouraging them to use a low-fluoride toothpaste increased their caries risk. In contrast, those in the more-deprived areas are less likely to be brushing daily and the encouragement to do so had a greater impact than the concentration of fluoride in the toothpaste. If the cost of toothpaste is a barrier to deprived families with young children, this might also partly explain the difference in association between deprived and nondeprived communities.

In the most-deprived quartile, provision of free fluoride toothpaste, whether containing low or high levels of fluoride, appeared to have an impact on the number of children experiencing tooth extractions. In the comparison group, 21% had extractions compared with only 14% for both groups receiving toothpaste. By encouraging the children to brush using a fluoride toothpaste, the rate of progression of caries may have been reduced enough to negate the need for extractions. The provision of fluoride toothpaste had little impact on caries of the upper primary incisors. This type of caries is strongly associated with specific infant feeding patterns (9) and without modifying these behaviours the use of fluoride toothpaste appears to have little impact.

The attrition rate in lengthy studies involving such young children is inevitably high. Only 3731 of the panel of 7422 eligible children were examined and still participating in the study at its conclusion. Of these children, 3467 had postcodes sufficient to allow geographical linking to the deprivation data. Thus only 47% of the children recruited were involved in the final analysis for this part of the study. The majority of children lost to

the study were withdrawn as they had moved out of the study area ($n = 1432$, 19%). It should also be noted that a total 641 participants (9%) were lost in the two intervention groups provided with free toothpaste because of withdrawal of consent before the start of the programme. As the comparison group did not formally consent to participation in the study until they were due to be examined, the attrition rate was slightly higher in the two test groups than the comparison. This difference in attrition rate may have resulted in some selection bias in the study but this is difficult to quantify. To some extent the attrition rate in this study is an integral part of its evaluation. The external validity of the study is also difficult to quantify. Clearly this was a highly selected population with some of the highest levels of caries and deprivation in the UK (1).

There is some disagreement whether a programme of this type should supply toothpaste containing low (<600 ppm F) or high (1450 ppm F) levels of fluoride. It has been argued that young children should not be encouraged to use high-fluoride toothpaste because of the potential risk of fluorosis (10). However, the anticaries efficacy of low-fluoride toothpastes is questionable (11, 12) and, although supplying children with a toothpaste of this type might reduce the risk of fluorosis, it could also increase the risk of caries and thus negate the effectiveness of the programme. As the study population was generally considered to be at high caries risk, it was deemed appropriate for them to use a high-fluoride toothpaste with the advice that parents should supervise brushing and use a pea-sized amount of paste. However, it is clear that parents do not always supervise the brushing of their children's teeth and may not use a pea-sized amount of paste. The risk of fluorosis from participation in this programme is currently being determined and this information will provide a clearer understanding on the risks and benefits of programmes of this type.

It is concluded that the relative benefits of the programme considered in this study are different and dependent on the deprivation status of the participants. For the most-deprived groups, postal provision of either a low- or high-fluoride toothpaste provides similar levels of benefit. In the least-deprived group, only provision of a high-fluoride toothpaste provided a benefit. The absolute caries reduction seen for provision of the high-fluoride toothpaste was not related to the deprivation status and hence the programme did not reduce deprivation-related health inequalities. Targeting, using the methods employed in this study, is unlikely to improve the effectiveness of the programme.

Acknowledgements

This study report complies with the requirements of the CONSORT statement (http://www.consort-statement.org).

References

1. Pitts NB, Palmer JD. The dental caries experience of 5-year-old children in Great Britain. Surveys coordinated by the British Association for the Study of Community Dentistry in 1993/94. Community Dent Health 1995;12:52–8.
2. Davies GM, Worthington HV, Ellwood RP, Bentley EM, Blinkhorn AS, Taylor GO et al. A randomised controlled trial of the effectiveness of providing free fluoride toothpaste from the age of 12 months on reducing caries in 5–6 year old children. Community Dent Health 2002;19:131–6.
3. Ellwood RP, O'Mullane DM. Identification of areas with high levels of untreated dental caries. Community Dent Oral Epidemiol 1996;24:1–6.
4. Tickle M, Brown P, Blinkhorn A, Jenner T. Comparing the ability of different area measures of socioeconomic status to segment a population according to caries prevalence. Community Dent Health 2000; 17:138–44.
5. Mitropoulos C, Pitts NB, Deery C. British Association for the Study of Community Dentistry criteria for the standardized assessment of dental health (1992/93). In: BASCD trainers pack for caries prevalence studies 1992/93. Dundee: University of Dundee; 1992.
6. Townsend P, Phillimore P, Beattie A. Health and deprivation: inequalities and the North. London: Croom Helm; 1988.
7. Locker D. Deprivation and oral health: a review. Community Dent Oral Epidemiol 2000;28:161–9.
8. Jones S, Hussey R, Lennon MA. Dental health related behaviours in toddlers in low and high caries areas in St Helens, north west England. Br Dent J 1996; 181:13–7.
9. Davies GM, Blinkhorn FA, Duxbury JT. Caries among 3-year-olds in Greater Manchester. Br Dent J 2001;190:381–4.
10. British Society of Paediatric Dentistry. A policy document on fluoride dietary supplements and fluoride toothpastes for children. Int J Paediat Dent 1996;6:139–42.
11. Ellwood RP, Blinkhorn AS, Davies RM. Fluoride: how to maximize the benefits and minimize the risks. Dent Update 1998;25:365–72.
12. Ammari AB, Bloch-Zupan A, Ashley PF. Systematic review of studies comparing the anticaries efficacy of children's toothpaste containing 600 ppm of fluoride or less with high fluoride toothpastes of 1000 ppm or above. Caries Res 2003;37:85–92.