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Challenges associated with the evaluation of a dental health promotion programme in a deprived urban area

G.M. Davies[1], J.T. Duxbury[1], N.J. Boothman[1] and R.M. Davies[2]

[1]*Manchester Primary Care Trust, Manchester, UK;* [2]*Dental Health Unit, Manchester,UK.*

Objective This paper reports the results of a community trial to measure the clinical impact of a linked series of interventions on Early Childhood Caries (ECC) and general caries levels among five-year-old children. It exemplifies the problems of undertaking population based interventions in deprived communities. ***Research design*** Two health districts (Primary Care Groups) were matched for dental disease levels and socio-demographic factors. One was randomly allocated to be the active intervention PCG, the other the comparison PCG. Children in the active PCG received a series of interventions to support positive dental health behaviour from the age of 8 to 32 months. Clinical examinations were undertaken on a cohort of 5-year-old children in both active and comparison PCGs. ***Setting*** In the active PCG, children who attended designated clinics for their 8-month developmental checks and/or MMR inoculations at 12 to 15 months, were given gift bags, the first contained a trainer cup, the second fluoride toothpaste (1450 ppm F) and toothbrush. Parents were also given written, pictorial and verbal advice on oral care. Further supplies of toothpaste and brushes were posted to the children's homes at 20, 26 and 32 months. When five years of age children in the two PCGs were examined in school. ***Outcome measures*** Severity and prevalence of ECC and general caries. Levels of participation. ***Results*** Among participants in the active PCG the prevalence of ECC, general caries and extraction experience and mean dmft (20%: 54%: 3%: 2.2) were lower than in 'participants' in the comparison area (32%: 64%: 12%: 3.7). All differences were statistically significant. When all children (participants and non-participants) in the two PCGs were compared, the differences were much reduced (30%: 63%: 6%: 3.1 vs. 32%: 64%: 12%: 3.6). A higher proportion of children in the active PCG area (47%) were found not to have participated in the interventions, when compared to 21% in the comparison area. Disease levels in the non-participants in the active PCG were particularly high. The impact of participation bias, changes in baseline balance, population mobility and alternative study design on outcomes are explored. ***Conclusion*** The impact of non-participation in a deprived, urban conurbation with high levels of population mobility are sufficient to dilute the impact of a health intervention such that few benefits are discernible at a population level.

Key words: caries, dental health promotion, participation, research methodology

Introduction

The search for effective interventions to reduce inequalities in dental health has been a priority for many years and has been given fresh impetus by the UK government and the setting of targets for health improvements by Primary Care Trusts (PCTs).

The lack of evidence of effectiveness of population based dental health promotion programmes, with the exception of water fluoridation, has left decision-makers and service commissioners with few choices. Kay and Locker (1998) and Watts *et al* (2001) concluded that the evidence that dental health education provides a measurable health gain was sparse. However, it is widely accepted that interventions which involve greater availability of fluoride are more likely to provide benefits.

It is advised that all health promotion activity should be targeted at the root cause of a problem, involve the target community in the early planning stages, be holistic in approach and empower the community to make healthier choices. Interventions should also involve activity for which there is robust scientific evidence of their effectiveness as a public health tool. In the absence of such evidence the intervention should be evaluated in a sufficiently robustly designed study to minimise the effects of bias and the likely effects seen by clusters of individuals receiving health interventions. Few examples of such practice can be found in the literature (Petersen and Kwan, 2004). The intervention described in the present paper was instigated in response to the high levels of Early Childhood Caries (ECC) and general caries found in the Manchester child population (Davies *et al*, 2001). Positive results of behavioural evaluation among parents and clinical outcomes among three year-olds have previously been reported (Davies *et al*, 2005). This study allowed a series of interventions to occur with timely, simple advice being given, a single message at a time, to parents of young children. The intervention is aimed at all children aged 8–32 months in the population and has been running for five years. It was hoped that the programme would reduce the prevalence and severity of caries in the primary dentition of five-year olds. This study highlights some of the issues that threaten such an undertaking and its evaluation at community level.

The aim of this study was to measure the clinical impact of a linked series of interventions on ECC and general caries levels in a community of five-year-old children.

Correspondence to: Dr G.M. Davies, Dental Dept, Manchester Primary Care Trust, Mauldeth House, Mauldeth Road West, Manchester, M21 7RL. Email: gill.davies@manchester..nhs.uk

Method

Details of the series of interventions and the design of this study have been reported previously (Davies *et al*, 2005). Briefly, a multi-stage intervention programme was introduced to pre-school children in the non-fluoridated city of Manchester, UK. The aim was to assess the effectiveness of the programme in reducing caries levels in the five-year-old population. Two Primary Care Group (PCG) areas were matched for disease levels and several socio-demographic factors including the proportion of Asian children. This last factor had previously been shown to be relevant as higher levels of ECC are found among children of Asian background (Davies *et al*, 2001). One PCG was randomly allocated to receive the series of interventions, the other served as a comparison area. Ethical approval was granted from Manchester Local Research Ethics Committee.

The series of interventions involved health vsitors giving dental health advice and gift bags to parents when babies received their 8-month developmental checks and/or attended clinics for MMR vaccinations at 12-15 months. The '8-month' bags contained trainer cups with leaflets to encourage the use of safe drinks and the 'MMR bags' contained toothpaste and brushes with leaflets encouraging the early commencement of twice daily supervised brushing. All leaflets were supplied with translations into seven of the most common local languages. Participants were identified as having made an attendance for these routine health checks from the Child Health System (CHS) database; non-participants were those who attended neither of the health checks and consequently would not have received the intervention programme. Participants in the intervention area also received, through the post, toothpaste, containing 1450 ppm F, and a toothbrush when they were 20, 26 and 32 months old with leaflets supporting continued brushing. Potential participants in the comparison area who had attended for their health checks received none of the interventions. The interventions were started in 1999.

A cohort of children who were born between October 1998 and June 1999 were examined in schools in the intervention and comparison areas when they were five years old. All state run primary schools formed the population sampling frame and random sampling of these, weighted for school size, was undertaken. Random sampling of all age-eligible children in sampled schools was then done for the larger schools to produce the sample. Only three parents declined permission for their children to be examined. The power calculation dictated that 214 children in both test and control groups would need to be examined in order to detect a 25 per cent difference in prevalence of caries experience, with 95% power.

Two examiners, who were trained and calibrated to BASCD standards (Pine *et al*, 1997) visited schools in a variety of locations during an examining day and were blind to the participation level of each child. They recorded caries at the dentinal level using visual criteria alone, with the child supine, light being provided by a Daray lamp on its higher setting and drying by means of cotton wool rolls (Pitts *et al*, 1997). Children were recorded as having ECC if one or more carious lesions were present on one or more upper anterior teeth (Davies *et al*, 2001)

Comparisons were made between participants in both the intervention and comparison areas, between the non-participants in both areas and finally between all the children examined in the two PCGs. Independent t-tests were used to detect differences between mean values and Chi square test tested differences in proportions. The α level of 0.05 was used.

Results

Analysis of the baseline factors used initially to match the PCG areas was repeated at the time of final examination. Table 1 shows that unemployment and deprivation levels have remained matched and the prevalence and severity of caries are similar. The proportion of five-year-old Asian children increased during the study period in the intervention PCG area and then matched the level found in the comparison area more closely.

Analysis of participants

In the intervention area a total of 842 children were examined, 253 of whom had attended for their 8-month developmental check and/or their MMR vaccination and received the intervention programme. In the comparison area, 286 children were identified as potential participants having attended clinics for their health checks. A comparison of these participant children demonstrated differences in the prevalence and severity of caries (Table 2). The prevalence of caries experience in participants in the intervention group was 54% compared with 64% in the comparison group ($p=0.03$).

The mean dmft of participants in the intervention area was 2.23 compared with 3.72 ($p<0.0001$) among potential participants in the comparison area, a difference of 40%. In the intervention group 20% of participants had one or more carious lesions involving their upper anterior teeth (ECC) compared with 32% in the comparison group ($p=0.002$). Three percent of children in the intervention group had had extractions compared with 12% in the comparison group ($p<0.0001$).

Analysis of non-participants

Analysis of children for whom there was no evidence of their having fulfilled requirements for participation is shown in Table 3. More children had failed to participate in the intervention area (224, 47%) than in the comparison area (79, 21%). The prevalence and severity of caries were highest among non-participating children in the intervention area (73%, dmft 4.1). Similarly, a higher proportion (40%) of non-participating children in the active area had ECC compared with 30% in the comparison area.

Community level analysis

When data from all the children were analysed, regardless of whether they participated or not, the differences were no longer apparent (Table 4). The prevalence and severity of general caries and ECC among children in the intervention area were 63%, 3.12 and 30% respectively compared with 64%, 3.60 and 32% in the comparison area. Six percent of children in the intervention area had experienced extractions compared to 12% in the comparison population.

Table 1. Comparison of baseline balance factors at start and finish of study period in test and comparison PCG areas

	Unemployment		*Mean Index of Multiple deprivation*		*% sampled 5 yr olds of Asian origin*		*Mean dmft of 5 yr olds*		*% caries experience*	
	Test	*Comparison*	*Test*	*Comparison*	*Test*	*Comparison*	*Test*	*Comparison*	*Test*	*Comparison*
1997/98	24.20	21.59	53.58	66.06	23	27	3.4	3.4	65	68
2003/04	8.1	8.2	52.94	65.42	29	27	3.1	3.6	63	64

Table 2. Caries severity and prevalence in participants in test and comparison PCG areas

	Mean dmft (s.d.) *[95% CI]*	*Caries experience dmft>0*		*Proportion with nursing caries*		*Experience of extraction*	
		n	*(%)*	*n*	*(%)*	*n*	*%*
Children identified as participants in test area n=253	2.23 (3.25) [1.84, 2.62]	138	(54)	51	(20)	7	(3)
Children identified as "participants" in comparison area n=286	3.72 (4.17) [3.23, 4.21]	183	(64)	93	(32)	35	(12)
p values	*<0.0001* *40% reduction*	*0.03*		*0.002*		*<0.0001*	

Table 3. Caries severity and prevalence among non-participants in test and comparison communities

	Mean dmft (s.d.) *[95% CI]*	*Caries experience dmft>0*		*Proportion with nursing caries*		*Experience of extraction*	
		n	*(%)*	*n*	*(%)*	*n*	*%*
Non- participating children in test PCG area n=224 (47%)	4.11 (4.15) [3.56, 4.66]	165	(73)	90	(40)	22	(10)
Non- participating children in comparison PCG area n=79 (21%)	3.16 (3.41) [2.40, 3.92]	50	(63)	24	(30)	10	(13)
p values	*0.07*	*0.11*		*0.16*		*0.6*	

Discussion

The intervention programme was intended for all pre-school children in the active PCG area and it was anticipated that attendance for the 8-month developmental check and/or MMR vaccination would achieve good penetration. In fact, during the period of the study, 83% of children in the birth cohort received MMR vaccinations in the test PCG and 84% in the comparison PCG. However, by the time of clinical examination when the cohort of children reached the age of five years only 53% of children attending schools in the active area had fulfilled the criteria to participate and received the intervention programme. In the comparison area 79% had fulfilled the criteria. Whilst those who received the intervention programme in the active area had significantly lower prevalence of ECC and general caries and dmft than non-participants, when examined on a community basis the inclusion of the high proportion of non-participants (47%) removed these benefits.

The reasons for the high level of non-participants in the five year old population in the active area are currently being investigated.

The large difference seen in caries levels between those who received the intervention programme in the active area and those who fulfilled the criteria for par-

Table 4. Comparison of caries severity and prevalence among all children in the test and comparison communities

	Mean dmft (s.d.)	*Caries experience dmft>0*		*Proportion with nursing caries*		*Experience of extraction*	
	[95% CI]	*n*	*(%)*	*n*	*(%)*	*n*	*%*
Test PCG area n=477	3.12 (3.82) [2.79, 3.45]	302	(63)	141	(30)	29	(6)
Comparison PCG area n=365	3.60 (4.02) [3.19, 4.01]	233	(64)	117	(32)	45	(12)
Total sample n=842	3.33 (3.91)	535	(64)	258	(31)	74	(9)
p values	*0.08*	*0.9*		*0.5*		*0.002*	

ticipation in the comparison area must be viewed with caution (Table 2). It is tempting to attribute some of the differences to the intervention programme alone but other factors should be considered. The high levels of non-participation in the test area suggest that those who did participate and remained in the area were the more settled families with possibly better health related behaviours. If this is the case then the improvement in dental health may, at least in part, simply be a bias caused by the participation criteria and longevity of residence.

The highest levels of general caries and ECC were found among non-participant children examined in the active intervention area. ECC experience was exceptionally high (40%) and extraction experience was also increased compared with other children (10% vs 3%). Among similar non-participant children in the comparison area the caries levels are more like that of the rest of the population. This high level of disease among a high proportion of the population meant that few benefits on a population basis could be seen. Non-participation clearly acts as a barrier to efforts to reduce dental disease on a population basis. The findings of the previous study of three-year-olds involved in this intervention are repeated here, but with more pronounced differences in clinical terms and in participation effects (Davies *et al*, 2005).

The involvement of only one pair of matched areas severely limits the strength of the findings in this study. The preferred design would be of at least twenty pairs of matched areas, each having a randomly allocated test and control group. All test areas would have the same interventions provided in identical ways and contamination of all control sites by other dentally related programmes would be prevented for the duration of the study. The establishment, maintenance and evaluation of such a project would certainly be challenging. For example, in this study a second pair of localities for evaluation was started but contamination by external dental initiatives precluded its inclusion. Within the localities under scrutiny, changes in health visiting practice and possible changes to postal charges both serve to impact severely on the future delivery of the series of interventions being evaluated. Such outside forces could act on all of the 20 pairs needed for a valid study, thus threatening the validity of the outcome.

In conclusion, this study reinforces the problems of achieving community benefit from a health promotion project conducted in a deprived urban setting (Davies *et al*. 2005) with high levels of population mobility. Under such circumstances, whilst a particular intervention may have impact on those who participate, it is almost impossible to make a difference to population measures of health. It is difficult to draw firm conclusions when participation bias is present and baseline balance and other socio-demographic factors shift. The implementation of a multi-site cluster controlled study would go some way to overcome some of the research design limitations but others would persist and possibly jeopardise the whole undertaking.

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