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Conducting trials

Sir, as co-ordinators of the eleven year-old PREP (Product Research and Evaluation in Practice) Panel, a UK - wide research group of currently 25 enthusiastic General Dental Practitioners (GDPs), we were interested to read the paper 'The advantages and disadvantages of running a clinical trial in general practices' (*BDJ* 2004,**197**:311–313) and the accompanying comments of the Editor (*BDJ* 2004,**197**: 289).

We admire the ambitious original protocol and envy the understanding Ethics Committee. The experiences of the PREP Panels are well documented[1-3], after over 40 clinical evaluations of materials and techniques, and also three, one- and two-year clinical trials of restorative materials. The clinical trials have all been reported in peer-reviewed journals. Our own experiences also contributed to the paper co-authored in 2002[4] on research in dental practice.

Some of the factors that we found useful were:

a) The number of practitioners was kept small (around six) to aid monitoring and communication.
b) The trial material was first used for a familiarisation period so both operator and dental nurse were fully conversant with the manufacturers' instructions.
c) The clinicians were paid a realistic fee for the additional time involved per patient visit and a fee was also paid to the patient for their expenses in attending recall appointments (last trial – 88% recall rate at 2 years).

The GDPs seem to bear the brunt of the criticism in Dr Jones' paper (practitioners using clinical judgement as to what was in their patients' best interests!), some of which we feel is unwarranted. It would have been interesting to hear the GDPs' points of view e.g. organisation of the trial, ease of use of the material, adequacy of remuneration for their and their patients' time, support from the co-ordinators etc.

It is, however, worth recalling that in our first one-year trial we encountered an interesting diversion from the protocol (a compomer restorative material was incorrectly being placed in load-bearing situations) and these results were analysed separately, leading to the manufacturer's further development of the material to react to the use, now common, of the material in this way.

The majority of readers of the *BDJ* are GDPs and they want to know how materials perform in general practice. We agree with the authors that, despite their less-than-rosy experiences in working with practitioners, there is a need for the profession to set up a way of conducting trials in general practices and also to avoid duplication of past negative experiences.

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One of the authors of the paper, Dr C S Jones responds: *We thank Dr R. J. Crisp and Professor Burke for their interest in our paper and for the information on the factors they found helpful in running the PREP panel.*

We are aware of the success of this panel; indeed the test material in our study was evaluated by that panel. Furthermore, two of us were involved with the successful use of GDPs to evaluate materials by Peter Knibbs in the 1980s [1-3]. In consequence, the three factors they mention were at the fore-front of our mind in establishing the protocol.

a) The number of practitioners was small. About six were involved at any one time although we replaced those from whom we received few or no results.
b) The materials were provided for familiarisation before the start. In fact a session was devoted to meeting the GDPs and providing them with an opportunity to handle the material and additionally comment on the protocol. These comments were then included in the final study design. A pilot study had also been carried out with one GDP prior to the initial discussion.
c) The amount of surgery time involved was discussed in respect of the level of remuneration and was agreed with the participants before the start.

However there is a difference between clinical evaluations as carried out by the PREP panel and in Knibbs et al *on single materials and a controlled clinical trial which was the objective here.*

We did not intend to imply that practitioners should not exercise clinical judgement as to what was in their patients' best interests but the object of this clinical trial was to compare the use of a metal reinforced glass-ionomer cement as an alternative to amalgam in the permanent dentition. To get a valid assessment of the trial material it was necessary to place the restorations alternately accepting that the two materials might be used under the similar clinical conditions. Unfortunately other exclusion criteria appeared to have been adopted despite our attempts to circumvent this prior to the commencement of the trial. Apart from two practitioners, the restorations were not placed alternately. If the exercise of clinical judgement were based on finding that the performance of the test material was poor, this would be entirely proper. We would have expected this to be reported and participant(s) to withdraw. We received no such reports; nor did it

come up in discussions with coordinators either initially or during the trial. In the light of this we feel that we were possibly trying to 'go a bridge too far'.

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Toothwear and erosion

Sir, I read the paper on toothwear/erosion, water fluoridation and deprivation (*BDJ* 2004, **197**: 413) with interest. Although correctly described as the first to investigate fluoridation and erosion in the UK, it was preceded by a study in Ireland[1] last year. A number of flaws require highlighting, to enable the results to be taken in context.

The authors correctly state that epidemiology studies are difficult to compare due to a wide range of indices used, but then use a new index and index teeth (canines), instead of following other National conventions[2]. They further muddy the waters by referring to tooth wear, erosion and smooth surface tooth wear. The latter two being the same thing. They then confuse and compromise their results by excluding molar data on the basis that attrition plays a part. Yet the differentiation between attrition and erosion on these surfaces is clear [3-5], and a greater amount of erosion has been identified on these surfaces than incisors[6].

The literature on erosion and social class is not conflicting. For the permanent dentition in children, studies have found a significant correlation [2,7-11]. The paper quoted involving primary dentitions can be dismissed as it was based upon social class of school area and not examinees residence, whereas others found a positive relationship[1,12] or no difference[2,13] between social groups.

All results quoted, are for fluoridation status at the time of examination (2,351 children) and not for those with lifelong exposure to Fluoride (n – 1,331). This is a fundamental flaw. Although no results are provided this is dismissed in one sentence, confirming life long exposure did not result in a significant reduction in erosion.

Comparisons are made with the results of Teo *et al*[14]. This paper should be discounted as only 96 individuals were examined, 67% of the Fluoridated group were aged 12 to 29 years, whilst 72.3% of the non-fluoridated residents were aged 30 to 60+, making any results a complete nonsense.

Stating 'the risk of smooth surface tooth wear (erosion) is decreased by a factor of 1.5 by water fluoridation' infers that children who have the same consumption rates of acidic drinks are at less risk by 1.5 times. But if they are drinking pop, they are not drinking the fluoridated water and thus not gaining from the effects.

It is known that gender, ethnicity, deprivation and consumption of carbonated drinks has an effect on the prevalence of erosion[11,15]. Thus when investigating a further factor such as the effect of fluoridation, these factors have to be controlled and balanced when choosing the case and control samples. Any results otherwise obtained, such as in this study, must be taken with a large pinch of salt.

The critical pH of hydroxyapatite is 5.5 and fluorapatite 4.5. Many acidic foods and drinks have a pH way below these, with a rapid and blanket effect, so the logical conclusion is that fluoridation should have little or no effect on the prevalence of erosion as in Ireland[1].

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2. HMSO London 2000; NDNS study 4-18 yr olds
3. Clin Prev Dent 1987; 9: 12-16
4. Dent Update 1982; August: 373-381
5. J Dent Child 1998; 65: 484-486
6. Dugmore C. PhD Thesis 2002. U. Birm
7. Comm Dent Hlth 1994; 11: 83-86
8. J Rest Dent 2000; 79 1172 (Abs)
9. BDJ 2001; 190: 145-149
10. IJPD 2003; 13: 295-303
11. BDJ 2004; 196: 279-282
12. Comm Dent Hlth; 1995; 12: 161-166
13. Taylor C. MCDH Dissertation. 1996. U.Birm
14. Aust Dent J 1997; 42: 92-102
15. BDJ 2004; 196: 283-286

One of the authors of the paper, Dr A Milosevic responds: *There is no 'national convention' for measurement of wear although the national survey did examine the labial and palatal surfaces of the four upper incisors. The canines were included because twelve anterior teeth were reported to provide greater sensitivity and specificity in detecting wear cases[1]. Dr. Dugmore is partly correct regarding the degree of molar involvement. Occlusal surfaces of the first molars exhibit dentine exposure more commonly than palatal surfaces of incisors but it cannot be stated with any certainty that this is solely from acid erosion[2]. I personally suspect that cupped cuspal tips with exposed dentine are primarily eroded but cusp tips will contact opposing fossae in this age group. Excluding attrition on occlusal surfaces is impossible. I still believe, however, that first molars should be included in any index, as a marker of dentinal exposure and susceptibility to wear. We strongly disagree that 'the results are confused and compromised'.*

Although Dr. Dugmore states the literature regarding the relationship between erosion and social class is not conflicting, he cites several studies with different results.

Dr. Dugmore mis-read the number of children who benefited from fluoride since birth. Only 383 children were in this category from a total number of 1,344 who had been resident at the same address since birth. Changing homes reduced the number with life long exposure to fluoridated water significantly and perhaps a larger sample would have produced a different result.

Between group analysis (fluoridated & non-fluoridated) for consumption rates was not assessed and we made no claim regarding this. Children would probably drink diluted squash and drink water occasionally not to mention brush their teeth with tap water. Topical effects are more important than systemic at this age.

It is agreed that "gender, ethnicity, deprivation and consumption" may influence the prevalence of erosion. However, carrying out statistical analyses on sub-samples in our study would have resulted in reduced power and increased the risk of type II error.

Studies on erosion and abrasion in vitro *have found that fluoride reduces mineral loss[3-5]. It would be counter-intuitive if water fluoridation did not have a protective effect.*

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