# RESEARCH

#### IN BRIEF

- This study reports the views of GDPs and specialist paediatric dentists on how they would approach the care of young children presenting with a range of common clinical scenarios.
- Large variation was found in the treatment choices for the scenarios within both generalists and specialists.
- Different patterns in the approach to care were found when generalists and specialists were compared.
- This variation is at odds with an evidence based approach to healthcare.
- Randomised controlled trials are needed to identify the best way of treating young children with carious primary teeth.

# Approaches taken to the treatment of young children with carious primary teeth: a national cross-sectional survey of general dental practitioners and paediatric specialists in England

M. Tickle,<sup>1</sup> A. G. Threlfall,<sup>2</sup> L. Pilkington,<sup>3</sup> K. M. Milsom,<sup>4</sup> M. S. Duggal<sup>5</sup> and A. S. Blinkhorn<sup>6</sup>

**Aim** To measure the distribution of choices for the treatment of a child with differing severities of caries in a primary molar tooth among specialists in paediatric dentistry and general dental practitioners (GDPs) in England.

**Method** Two surveys were undertaken using the same tool. The populations invited to take part in the study were confined to dentists practising in England in 2004. They were 500 GDPs selected at random from the list of all GDPs with a National Health Service (NHS) contract identified by the Dental Practice Board (DPB) and all 148 specialists in paediatric dentistry appearing on the General Dental Council specialist register. The selected dentists were sent a questionnaire containing four hypothetical clinical case scenarios in which the severity of dental caries in a single primary molar differed. Each clinical case scenario had a list of possible treatment options and participants were asked to select their single most preferred treatment option. To maximise the response rate there were three mailing rounds.

**Results** Of the 500 GDPs and 148 paediatric specialists sent a questionnaire, 322 (64%) GDPs and 115 (78%) specialists responded. The answers to each of the case scenarios indicate differences of opinion both between and among GDPs and specialists in the care they would

<sup>17</sup>Professor of Dental Public Health and Primary Care, <sup>2</sup>DH Research Training Fellow, <sup>3</sup>Research Assistant, <sup>4</sup>Consultant in Dental Public Health, Oral Health Unit, National Primary Care Research and Development Centre, The University of Manchester, Williamson Building, Oxford Road, Manchester, M13 9PL; <sup>4</sup>Professor of Child Dental Health, Leeds Dental Institute, Clarendon Way, Leeds, LS2 9LU; <sup>6</sup>Professor of Oral Health, Oral Health Unit, National Primary Care Research and Development Centre, The University of Manchester, Williamson Building, Oxford Road, Manchester, M13 9PL <sup>\*</sup>Correspondence to: Professor Martin Tickle, Manchester University Dental School, Higher Cambridge Street, Manchester, M15 6LP Email: martin.tickle@manchester.ac.uk

Online article number E4 Refereed Paper – accepted 16 October 2006 DOI: 10.1038/bdj.2007.570 <sup>®</sup>British Dental Journal 2007; 203: E4 recommend for a child with caries in a primary molar tooth. This variation in opinion about care was more pronounced for a single deep carious lesion than for a less severe lesion. The spread of treatment options chosen in each scenario indicates disagreement among GDPs and specialists about restorative techniques and philosophy of care. **Conclusion** In England there is wide variation among GDPs and specialists in paediatric dentistry about the best way to treat a young child with caries in a primary molar tooth. Well designed studies are urgently needed to provide strong evidence for the most effective way to manage the dental care of children.

#### INTRODUCTION

Dental caries in the primary dentition is an important public health problem in the United Kingdom. The most recent national survey of the dental health of five-year-old children in England and Wales reveals that 40% had caries experience.<sup>1</sup> In the UK dental care is free for all children and is paid for by the National Health Service (NHS). Care is provided by GDPs, the Community Dental Service (CDS) and specialist paediatric dental services. Paediatric specialists are few in number and largely based in hospitals or the CDS. GDPs working within the General Dental Service (GDS) make up more than 80% of the dental profession and therefore these primary care dentists provide the majority of dental care for children.

UK guidelines produced by the British Society of Paediatric Dentistry (BSPD) recommend a comprehensive restorative approach to the management of children with carious primary molar teeth.<sup>2</sup> Data suggest that GDPs do not always follow this approach. For example, the NHS epidemiological surveys of the dental caries in five-year-old children in England and Wales coordinated by the British Association for the Study of Community Dentistry (BASCD) indicate that caries experience has remained at a similar level over the last 20 years but the provision of restorative care has fallen.1 The restorative index in the 2004/5 survey was 12%, however this summary statistic masked large variation in the restorative index across the country; at Primary Care Trust level (the smallest administrative units within the NHS) the restorative index ranged from 3-43%.1 Any uncertainty among dentists in the UK about the best way to provide care for young children with caries has been added to, following publication of the findings from two recent observational studies conducted in primary care. The first reported similar numbers of episodes of pain and extractions in restored and unrestored carious primary molars, the second reported that the majority of unrestored carious primary teeth remain symptomless until shed naturally.<sup>3,4</sup> These studies prompted an ongoing debate5-8 within the profession on how best to treat children with carious primary teeth, which is unresolved. The lack of a strong evidence base is unhelpful in this regard and the current research literature offers no clear guidance to dentists on how best to approach the care and treatment of young children with caries in their primary teeth. The extent to which differences of opinion among dentists, about how best to treat children with carious primary teeth, is responsible for the variation in the care offered to NHS patients is unknown.

Investigating variation among dentists in the care they offer young children is complicated by differences among children in both their levels of caries and their acceptance of dental procedures. For example, a treatment appropriate for a calm child may not be appropriate for a nervous child and a dentist may restore a carious tooth if the child has only one cavity but might not restore the tooth if the child has multiple cavities. Variations in the mix of patients seen by a dentist also make any observed differences in the number and types of treatments offered by a dentist difficult to interpret.

The aim of this study was to measure the variation in the approach to care of children with carious primary molar teeth taken by GDPs and specialists in paediatric dentistry practising in England. Clinical case scenarios were developed and used to survey the opinions of a national sample of GDPs and all specialists in paediatric dentistry in England about the care they would recommend for a child with a single carious primary molar tooth. In each scenario the child was always described as being calm and the level of disease was described. This standardisation of the patient allows us to attribute variation in treatment options selected for each scenario to differences in opinion about care among the participating dentists. If widespread differences of opinion about the care were found it would have important implications for postgraduate and undergraduate education, and the provision of guidelines. It would also be an important stepping stone towards informing the design of randomised control trials to find out the best way to treat children with carious primary molar teeth.

#### METHODS

This study used clinical case scenarios to survey opinions of GDPs and specialists in paediatric dentistry working in England in 2004 about the care to offer young children with carious primary molars. Two independent surveys were undertaken using the same methodology. For the first survey a simple, non-stratified random sample of 500 GDPs was drawn from all dentists working in England in the GDS who

Table 1	Summary of	f the case	scenarios and	the choice of	f responses
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	Description of	
Scenario	the scenario	Choice of responses
1	A six-year-old boy has a single distal occlusal cavity affecting less than half the marginal ridge in the lower right first primary molar tooth. The tooth is vital and the child has no history of pain.	<ul> <li>No restorative treatment</li> <li>Fluoride varnish application</li> <li>Atraumatic restorative technique</li> <li>Traditional restorative treatment</li> <li>Vital pulpotomy with glass ionomer/composite or amalgam restoration</li> <li>Vital pulpotomy with stainless steel crown</li> <li>Extraction under local anaesthetic</li> <li>Refer for extraction under sedation</li> <li>Refer for extraction under general anaesthetic.</li> </ul>
2	A six-year-old boy has a single distal occlusal cavity affecting more than half of the mar- ginal ridge in the lower right first primary molar tooth. The tooth is vital and the child has no history of pain.	<ul> <li>No restorative treatment</li> <li>Fluoride varnish application</li> <li>Atraumatic restorative technique</li> <li>Traditional restorative treatment</li> <li>Vital pulpotomy with glass ionomer/composite or amalgam restoration</li> <li>Vital pulpotomy with stainless steel crown</li> <li>Extraction under local anaesthetic</li> <li>Refer for extraction under sedation</li> <li>Refer for extraction under general anaesthetic.</li> </ul>
3	A six-year-old boy has a large distal occlusal cavity in a lower right first primary molar, which is non-vital and has an associated sinus. He has no his- tory of pain.	<ul> <li>No restorative treatment</li> <li>Fluoride varnish application</li> <li>Atraumatic restorative technique</li> <li>Traditional restorative treatment</li> <li>Open the pulp chamber and drain the tooth</li> <li>Non-vital pulpotomy with glass ionomer/composite or amalgam restoration</li> <li>Non vital pulpotomy with stainless steel crown</li> <li>Prescribe antibiotics alone</li> <li>Extraction under local anaesthetic</li> <li>Refer for extraction under general anaesthetic.</li> </ul>
4	A six-year-old boy has a large distal occlusal cavity in a lower right first primary molar where more than half of the marginal ridge has been destroyed. He is experiencing pain. NB: Dentists were asked to give their preferred treatment options to immediately relieve the child's pain.	<ul> <li>Open the pulp chamber and drain the tooth</li> <li>Excavate caries and place a sedative temporary dressing</li> <li>Prescribe antibiotics only</li> <li>Prescribe analgesics only</li> <li>Prescribe both antibiotics and analgesics</li> <li>Extraction under local anaesthetic</li> <li>Do nothing immediately but refer for extraction under sedation</li> <li>Do nothing immediately but refer for extraction under general anaesthetic.</li> </ul>

had received payment from the NHS for treatments performed on primary teeth. In order to comply with the Data Protection Act the sampling and the distribution of the case scenarios to the GDPs was undertaken by the Dental Practice Board (DPB), which is the body that pays NHS GDPs in England. For the second survey all 148 paediatric dental specialists appearing on the General Dental Council's specialist list and practising in England were included. Each selected dentist was sent a questionnaire containing four hypothetical clinical case scenarios in which the severity of dental caries in a primary molar differed. The case scenarios were originally developed for a qualitative study which investigated the care that 93 GDPs practising in the North West of England offered to young children.<sup>9</sup> The case scenarios were agreed following discussion with a reference panel that included five GDPs, three specialists in paediatric dentistry and two consultants in dental public health, and are designed to reflect a cross section of common dental conditions found in young children. In the original qualitative study participating dentists were asked to write down in detail the care they would provide to the child described in each scenario. These written answers were used to create the list of treatment options in each of the four case scenarios used in this study.

Before either of the surveys began, a piloting exercise was undertaken in which the questionnaire containing the four case scenarios was given to five GDPs to fill in and comment on the legibility and appropriateness of the questionnaire. The GDPs added no additional treatment options to any of the case scenarios and no changes were made.

In each of the four case scenarios participating dentists were instructed to select one treatment option from the list of treatment options presented. The case scenarios and treatment options are presented in Table 1.

Case scenario one described a six-year-old boy who had a single distal occlusal cavity affecting less than half the marginal ridge in a lower right first primary molar which was vital and he was described as having no history of pain. The treatment options were: i) no restorative treatment, ii) fluoride varnish application, iii) atraumatic restorative technique, iv) traditional restorative treatment, v) vital pulpotomy with glass ionomer/composite or amalgam restoration, vi) vital pulpotomy with stainless steel crown, vii) extraction under local anaesthetic, viii) refer for extraction under sedation, and ix) refer for extraction under general anaesthetic.

Case scenario two described a six-year-old boy with a single distal occlusal cavity that was affecting more than half of the marginal ridge in a lower right first primary molar which was vital and he was described as having no history of pain. The treatment options were: i) no restorative treatment, ii) fluoride varnish application, iii) atraumatic restorative technique, iv) traditional restorative treatment, v) vital pulpotomy with glass ionomer/composite or amalgam restoration, vi) vital pulpotomy with stainless steel crown, vii) extraction under local anaesthetic, viii) refer for extraction under sedation, and ix) refer for extraction under general anaesthetic.

Case scenario three described a six-year-old boy with a large distal occlusal cavity in a lower right first primary molar, which was non-vital and had an associated sinus and he was described as having no history of pain. The treatment options were: i) no restorative treatment, ii) fluoride varnish application, iii) atraumatic restorative technique, iv) traditional restorative treatment, v) open the pulp chamber and drain the tooth, vi) non-vital pulpotomy with glass ionomer/composite or amalgam restoration, vii) non vital pulpotomy with stainless steel crown, viii) prescribe antibiotics alone, ix) extraction under local anaesthetic, x) refer for extraction under sedation, and xi) refer for extraction under general anaesthetic.

	GDPs		Specialists	
Treatment option	Number	%	Number	%
No restorative treatment	17	5.4	0	0
Fluoride varnish application	6	1.9	2	1.9
Atraumatic restorative technique	180	57.3	13	12.1
Traditional restorative treatment	109	34.7	76	71.0
Vital pulpotomy with glass ionomer or composite or amalgam	1	0.3	5	4.7
Vital pulpotomy with stainless steel crown	1	0.3	11	10.3
Extraction under local anaesthetic	0	0	0	0
Refer for extraction under sedation	0	0	0	0
Refer for extraction under general anaesthetic	0	0	0	0

## Table 2 The treatments selected by 314 GDPs and 107 specialists for treating the child described in case scenario one

### Table 3 The treatments selected by 318 GDPs and 112 specialists for treating the child described in case scenario two

Treatment ontion	GDPs		Specialists	
Treatment option	Number	%	Number	%
No restorative treatment	7	2.2	0	0
Fluoride varnish application	3	0.9	0	0
Atraumatic restorative technique	111	34.9	5	4.5
Traditional restorative treatment	168	52.8	27	24.1
Vital pulpotomy with glass ionomer or composite or amalgam	21	6.6	25	22.3
Vital pulpotomy with stainless steel crown	5	1.6	55	49.1
Extraction under local anaesthetic	2	0.6	0	0
Refer for extraction under sedation	1	0.3	0	0
Refer for extraction under general anaesthetic	0	0	0	0

Case scenario four described a six-year-old boy with a large distal occlusal cavity in a lower right first primary molar where more than half of the marginal ridge has been destroyed and he was described as experiencing pain. Dentists were

treating the child described in case scenario three				
Treatment option	GDPs		Specialists	
Treatment option	Number	%	Number	%
No restorative treatment	20	6.3	2	1.8
Fluoride varnish application	0	0	0	0
Atraumatic restorative treatment	8	2.5	0	0
Traditional restorative treatment	0	0	0	0
Open the pulp chamber and drain the tooth	24	7.6	4	3.6
Non-vital pulpotomy with glass ionomer or composite or amalgam	159	50.3	24	21.8
Non-vital pulpotomy with stainless steel crown	14	4.4	57	51.8
Prescribe antibiotics alone	3	1.0	2	1.8
Extraction under local anaesthetic	80	25.3	19	17.3
Refer for extraction under sedation	7	2.2	2	2
Refer for extraction under general anaesthetic	1	0.3	0	0

Table 4 The treatments selected by 316 GDPs and 110 specialists fortreating the child described in case scenario three

Table 5 The treatments selected by 305 GDPs and 105 specialists for treating the child described in case scenario four

Treatment option*	GDPs		Specialists	
Treatment option"	Number	%	Number	%
Open the pulp chamber and drain the tooth	78	25.6	49	46.7
Excavate caries and place a sedative or a temporary dressing	36	11.8	6	5.7
Prescribe antibiotics only	30	9.8	2	1.9
Prescribe analgesics only	1	0.3	0	0
Prescribe both antibiotics and analgesics	46	15.1	14	13.3
Extraction under local anaesthetic	104	34.1	31	29.5
Do nothing immediately but refer for extraction under sedation	10	3.3	3	2.9
Do nothing immediately but refer for extraction under general anaesthetic	0	0	0	0
*to immediately relieve the child's pair	n			

asked to give their preferred treatment options to immediately relieve the child's pain. The options given were: i) open the pulp chamber and drain the tooth, ii) excavate caries and place a sedative temporary dressing, iii) prescribe antibiotics only, iv) prescribe analgesics only, v) prescribe both antibiotics and analgesics, vi) extraction under local anaesthetic, vii) do nothing immediately but refer for extraction under sedation, and viii) do nothing immediately but refer for extraction under general anaesthetic.

To avoid ambiguity, definitions of atraumatic and traditional restorative treatment were provided. Atraumatic restorative technique was defined as 'a treatment that involves the removal of soft, demineralised tooth tissue using predominately hand instruments followed by restoration of the tooth with glass ionomer and does not usually require the use of local anaesthesia.' Traditional restorative treatment was defined as 'a treatment that involves the complete removal of soft, demineralised tooth tissue using predominately rotary instruments, followed by restoration of the tooth with either glass ionomer/composite or amalgam and requires the use of local anaesthesia'.

To maximise the response rate there were three mailing rounds. Those who did not return their questionnaires in the previous round were sent a reminder and a new copy of the questionnaire to fill in and return. All data were treated with strict confidence and entered into a computer database. Analysis involved producing simple frequency distributions; no statistical tests were undertaken.

#### RESULTS

The fieldwork for this study was undertaken in the summer and autumn of 2005. Of the 500 general dental practitioners sent a questionnaire, 322 (64%) returned a completed questionnaire. Of the 148 specialists in paediatric dentistry sent a questionnaire, 115 (78%) returned a completed questionnaire.

The first scenario described a six-year-old boy who had a vital lower primary molar with a single distal occlusal cavity affecting less than half of the marginal ridge, but the child was not in pain. Of the dentists that returned a questionnaire, eight GDPs and eight specialists failed to correctly complete case scenario one. Table 2 describes the treatment choices from the options presented of the remaining 314 GDPs and 107 specialists. The findings from scenario one suggest that most GDPs and most specialists would restore this single small carious lesion in a compliant child; only 17 (5.4%) GDPs and no specialists opted for the no restoration option. The main difference of opinion among those taking the restorative approach was whether to restore the tooth using a traditional or an atraumatic technique. Among specialists, the traditional technique was the most preferred method (71.0%, n = 76) of restoration whereas among GDPs it was the atraumatic technique (57.3%, n = 180).

The second scenario described a six-year-old boy who had a larger single distal occlusal cavity, but the child was not in pain. Four GDPs and three specialists did not respond to this item. Table 3 describes the treatment choices from the options presented of the remaining 318 GDPs and 112 specialists. Only nine (3.1%) GDPs chose the options of no restorative approach or application of fluoride varnish. Among GDPs who said they would restore the tooth, the majority (52.8%, n = 168) opted for using a traditional restorative treatment, whilst just over a third (34.9%, n = 111) said they would use atraumatic restorative technique. Only 8.2% (n = 26) of GDPs would perform an elective, vital pulpotomy before restoring the tooth. Among specialists, the majority would undertake an elective vital pulpotomy (71.4%, n = 80) but there was a difference of opinion on the choice of restoration following the pulpotomy. Nearly a quarter (24.1%, n = 27) of specialists chose the option of traditional restorative treatment.

The third scenario described a six-year-old boy who had a non-vital tooth, with an associated sinus, but was not in pain. Six GDPs and five specialists failed to correctly complete this scenario. Table 4 describes the treatment choices of the remaining 316 GDPs and 110 specialists. Some 6.3% (n = 20) of GDPs and 1.8% (n = 2) of specialists selected a non-interventionist approach. The majority would intervene by undertaking a nonvital pulpotomy (GDPs: 54.7%, n = 173; specialists: 73.6%, n = 81), however over a quarter of GDPs (GDPs: 25.3%, n = 80; specialists: 17.3%, n = 19) would choose to extract the tooth under local anaesthetic.

The fourth case study described a six year old boy with a large carious cavity in a non-vital lower first primary molar and the child was experiencing pain. Seventeen GDPs and ten specialists failed to correctly complete this scenario. Table 5 describes the treatment choices from the options presented of the remaining 305 GDPs and 105 specialists. There was a difference of opinion as to whether to extract the tooth, open the tooth to obtain drainage or to leave the tooth untreated at this time and prescribe pharmaceuticals. Relatively large proportions in each group chose to prescribe pharmaceuticals alone (GDPs: 25.2%, n = 77; specialists: 15.2%, n = 16) when faced with this scenario. The most popular option for GDPs was extraction under local anaesthetic (34.1%, n = 104), whereas nearly half of specialists chose the option of opening the pulp chamber and draining the tooth (46.7%, n = 49). It is interesting to note that none of the participating dentists selected the option to refer the child for extraction under general anaesthesia.

#### DISCUSSION

This is the first study to use clinical case scenarios to survey the care that a national sample of GDPs and specialists in paediatric dentistry working within the NHS might offer to children with caries in their primary molar teeth. The purpose of this study was to detect, measure and describe variation in opinion on how GDPs and paediatric specialists approach the care of young children with carious primary molar teeth. Clinical case scenarios are hypothetical and can measure opinion about the care that might be provided in one particular case. They are not a tool for measuring the actual care a dentist would provide, as this will also be influenced by other factors that are not covered in a scenario, for example parental wishes. Therefore some caution is needed when interpreting the findings from this study. We interpret the variation shown in the answers to these case scenarios as indicating differences in opinion and possible uncertainty among GDPs and specialists about the best way to treat children with caries in their primary molars.

The response rate was 64% for the GDPs and 78% for the specialists and we acknowledge that those that did not respond might have provided different answers to the case scenarios. A higher response rate, especially among the GDPs would have been desirable, and the authors did consider undertaking analyses described in the literature to detect and correct non-response bias.<sup>10</sup> However, this approach was deemed to be unnecessary because even if all non-responders provided similar answers to the scenarios, the conclusion that there is substantial and important variation in choices of treatment among GDPs and among specialists and also differences between GDPs and specialists would remain the same.

The findings from scenario one suggest that most GDPs and most specialists agree that a single small carious lesion in a compliant child should be restored. Whilst there was broad consensus that a single carious lesion should be restored, there was a disagreement about the restorative technique. Among specialists the traditional technique was the most preferred method of restoration whereas among GDPs it was atraumatic restorative technique. In case scenario two the lesion is larger and again nearly all of the dentists would restore the tooth, but again there was disagreement about the method to be used. The specialists largely agreed that a vital pulpotomy should be undertaken followed by either the placement of a stainless steel crown or a plastic material. The GDPs were less inclined to choose a vital pulpotomy and most opted to traditionally restore the tooth. If these hypothetical choices mirror real-life prescribing habits, children attending specialists would be more likely to receive an elective, vital pulpotomy than children attending a GDP service.

In case scenario three a wide range of treatment options were selected but the majority of dentists would intervene either by extracting the tooth or by undertaking a pulpotomy. There was a clear difference between the specialists and the GDPs in the proportion selecting the option to restore the tooth with a stainless steel crown; just over 50% of specialists but less than five percent of the GDPs chose this option. Case scenario four, in which the child has a painful tooth, had the least agreement in the treatment options selected by the participants. There appears to be a difference of opinion as to whether to extract the tooth, open the tooth or to leave the tooth and prescribe pharmaceuticals. In those dentists choosing to first prescribe pharmaceuticals, opinion differs whether to prescribe antibiotics alone or with analgesics. This lack of consensus for providing effective and immediate care to ensure a young child is relieved of pain is a major cause for concern and has been commented upon by previous studies.11,12 However, there was agreement that doing nothing immediately and referring the child for extraction under general anaesthesia was not appropriate.

This study reveals differences of opinion not only about techniques but also philosophy of care among and between GDPs and specialists in paediatric dentistry. The extent to which the differences of opinion expressed in the answers to these case scenarios are reflected in differences in clinical practice can only be speculated upon. Several other factors, such as patients' expectations, training and the system of remuneration will also influence practice.13 National epidemiological data1 and activity data on delivery of care by NHS dental services<sup>14</sup> demonstrate that there are large differences in the levels of restorative treatment offered to children in adjacent parts of England and Wales and these differences cannot be explained by local differences in patient mix and dental workforce alone. From this study it seems likely that differences of opinion among dentists about the best way to manage similar conditions are contributing to the variation in care evident in the epidemiology and service activity data sets.

From a clinician's perspective it could be argued that each of the scenarios had a number of potentially correct treatment options. For example, for case scenario three it could be argued that opening the pulp chamber to drain the tooth, non-vital pulpotomy with or without a stainless steel crown and extraction under local analgesia are all potentially correct treatment options that will help the patient. Indeed, this might be the case. However, from a policy perspective, one treatment in each case scenario must either be better than the others in terms of the full range of patient outcomes or, if genuinely equivalent, one must be more cost effective for the health service to provide. It is also worth considering the child's perspective; many of the treatments described for each scenario will improve the child's oral health but the child's experience of dental care will depend upon the treatment received. For example, the findings from case scenario three suggest that a child with a large cavity in a non-vital first primary molar tooth could have the tooth restored, extracted or left alone depending upon which dentist they visit. From a child's perspective these treatments are qualitatively different and a child might find one treatment more traumatic than another. The long-term sequelae of different dental treatments on young children are not well understood, but it has been observed that extractions in young children are strongly associated with dental anxiety.15

Randomised control trials are accepted as being the gold standard for resolving uncertainty about the best way to treat patients with the same condition. In many branches of medicine, long cherished methods of treatment have been replaced by more effective treatments on the strength of the results of well constructed randomised trials. In paediatric dentistry, randomised trials are extremely rare and studies have tended to focus on comparing longevity of different restorations<sup>16</sup> rather than comparing the outcomes of very different approaches to care identified in this study. In this discussion we have not passed opinion on the appropriateness or not of the choices made by the GDPs and specialists, because of the lack of a strong evidence base. This lack of evidence hampers meaningful discussion about the best way to treat young children, and undermines the construction of evidence-based guidelines. Currently, guidelines for treating the carious primary dentition are based on inconclusive studies and the opinion of experts and as such, lack scientific credibility. For this situation to

improve there is an urgent need for new evidence from well constructed trials. This study suggests that the dental profession in England is in equipoise on how best to manage the care of a young child with a carious molar. This makes the ethical case for undertaking trials stronger than the ethical case for not undertaking trials. The different patterns of responses provided by generalists and specialists in this study provide some indication of what interventions should be compared in future randomised controlled trials.

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