FiCTION 07/44/03: QUESTIONNAIRES

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Page

CASE REPORT FORM

FiCTION
Fillings in Children's Teeth; Indicated Or Not

Area [ ][ ] Site [ ][ ] Participant [ ][ ][ ][ ] 1

The final character in the participant ID number gives you the randomly selected treatment arm. 1-9

Please remember that the randomly allocated treatment arm is the philosophy under which all treatment should be given.

Case Report Form

A CRF needs to be completed for each patient at each visit. A copy of ICDAS needs to be completed only at the first treatment visit and the final study visit.

1. Date of treatment

[ ][ ] D D [ ][ ] M M [ ][ ] Y Y 10-15

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2. Which treatment arm(s) were used today? *(Please circle all the numbers that apply)*.

Conventional	.....	1	16
Biological	.....	2	17
Prevention Alone	.....	3	18

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3. Do any of these arm(s) differ from the patient randomisation arm? (*Please circle the number that applies)*

Yes	.....	1	19
No	.....	2	

If you have answered "Yes", please complete a **Treatment Deviation Form (TDF)** and fax or post it back to NCTU marked for the attention of the FiCTION Trial Manager. Please file a copy of the **Treatment Deviation Form** along with the completed CRF in the patient's records.

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4. Reason for this visit? *(Please circle the number that applies).*

Baseline Appointment	……..	1	
Scheduled/Recall Appointment	.....	2	
Emergency/Unscheduled Appointment	.....	3	
Final Assessment	.....	4	20

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5. Appointment start time? [ ][ ][ ][ ] H H M M 21-24

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6. Appointment end time? [ ][ ][ ][ ] H H M M 25-28

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7. Was there a history of pain at this visit? *(Please circle the number that applies).*

Yes 1
No 2

If yes (Answer 7a)
If no (Go to question 8)

29

a. If yes was this likely to be due to: (please circle **yes** or **no** for each**)**

Caries (reversible or irreversible pulpitis), ... Yes_1 No_2 **If yes (Answer 7b)** 30

periradicular periodontitis etc.) 31

Other ..... Yes_1 No_2

(Erupting / exfoliating teeth, Trauma, Recurrent oral ulceration)

Please complete details for "other":…….

b. **Please circle which carious tooth/teeth you believe to be responsible for the pain:**

		55	54	53	52	51	61	62	63	64	65		
17	16	15	14	13	12	11	21	22	23	24	25	26	27
47	46	45	44	43	42	41	31	32	33	34	35	36	37
		85	84	83	82	81	71	72	73	74	75		

32

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8. Was there clinical evidence of dental infection i.e. abscesses or sinuses? *(Please circle the number that applies).*

Yes 1
No 2

If yes (Answer 8a)
If no (Go to question 9)

33

a. If yes was this: (please circle **yes** or **no** for each**)**

Sinus ..... Yes_1 No_2 34

Swelling ..... Yes_1 No_2 35

Pus from sulcus ..... Yes_1 No_2 36

If yes (Answer 8b)

b. **Please circle which tooth/teeth this dental infection involved:**

		55	54	53	52	51	61	62	63	64	65		
17	16	15	14	13	12	11	21	22	23	24	25	26	27
47	46	45	44	43	42	41	31	32	33	34	35	36	37
		85	84	83	82	81	71	72	73	74	75		

37

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9. Were radiographs taken at this appointment?

Yes 1
No 2

If yes (Answer 9a)
If no (Answer 9b)

38

a. Radiographic findings: (Please circle **yes, no** or **unclear** for each)

Peri-radicular Infection ..... Yes_1 No_2 $Unclear_3$ 39

Caries ..... Yes_1 No_2 $Unclear_3$ 40

Other ..... Yes_1 No_2 50

If "Other" please give details here:.....

b. Why were radiographs not taken?

Not due to be taken according to FGDP guidelines 1
Already taken during this course of treatment 2
Radiograph(s) not attempted (child compliance issues) 3
Parental wish 4
Attempted but failed 5
Other (please write in) 6

51

.....

10. Was any prevention provided at this visit? *(Please circle the number that applies)*

Yes	.....	1	**If yes (Answer 10a-c)**	
No	.....	2	**If no(Go to question 11)**	52

a. Who provided prevention at this visit? *(Please circle the number that applies, and then answer 10b and c)*

GDP	1
Dental Therapist	2
Dental Hygienist	3
Oral Health Educator	4
Childsmile/Extended Duty Dental Nurse	5
Someone else	6

If "Someone else" please write in their job title: 53

<u>This section should be completed by the person who provided the prevention:</u>

b. Prevention activities: Did you: (Please circle **yes** or **no** for each)

Brushing/Plaque Control Advice			
Advise adult strength toothpaste?	**Yes$_1$**	**No$_2$**	54
Advise dental floss	**Yes$_1$**	**No$_2$**	55
Recommend brushing twice daily	Yes1	No2	56
Recommend supervised brushing	**Yes$_1$**	**No$_2$**	57
Make a signed Action plan with the child/ carer re tooth brushing	Yes1	No2	58
Carry out "hands on" tooth brushing instruction with carer?	Yes1	No2	59
Carry out disclosing	**Yes$_1$**	**No$_2$**	60
Record plaque scores in the patients notes	Yes1	No2	61
Fissure Sealants			
Carry out preventive fissure sealants on permanent molars	Yes1	No2	62
Fluoride Varnish			
Apply fluoride varnish	**Yes$_1$**	**No$_2$**	63
Diet Investigation/Advice			
Ask the patient to complete a dietary investigation diary?	**Yes$_1$**	**No$_2$**	64
Investigate diet verbally	Yes$_1$	No$_2$	65
Recommend no more than 4 sugary attacks a day?	Yes1	No2	66
Explain about hidden sugars?	Yes1	No2	67
Recommend "safe" snacks?	Yes1	No2	68
Recommend "safe" drinks?	Yes1	No2	69
Make a signed Action plan with the child / carer re diet	Yes1	No2	70
Other: (please list)	**Yes$_1$**	**No$_2$**	71

.....

c. Approximately how long did you spend providing prevention? (in minutes) …… 72-73

11. Was operative treatment (i.e. any activity not covered under 10b) provided?

Yes	.....	1	**If yes (Answer question 11a and go to question 12 on the next page**
No	.....	2	**If no (Answer 13)**

74

a. Who provided operative treatment?

GDP	……..	1
Dental Therapist	…….	2

75

12. For each primary tooth operatively treated please complete the following using the FDI 2 digit notation as shown below: (Please circle **yes** or **no** for each)

2

9

Arm randomised to (C, B, P)		10

Primary Teeth										
upper right					upper left					
55	54	53	52	51	61	62	63	64	65	
85	84	83	82	81	71	72	73	74	75	
lower right					lower left					

	Treated Tooth 1		**Arm Used** (C,B,P)		**Treated Tooth 2**		**Arm Used** (C,B,P)		**Treated Tooth 3**		**Arm Used** (C,B,P)		**Treated Tooth 4**		**Arm Used** (C,B,P)		**Treated Tooth 5**		**Arm Used** (C,B,P)		**Treated Tooth 6**		**Arm Used** (C,B,P)	
FDI Tooth Number:																								
Caries Removal	11-12			13	35-36			37	59-60			61	83-84			85	107-108			109	131-132			133
Complete	**Yes**$_1$	**No**$_2$		14	**Yes**$_1$	**No**$_2$		38	**Yes**$_1$	**No**$_2$		62	**Yes**$_1$	**No**$_2$		86	**Yes**$_1$	**No**$_2$		110	**Yes**$_1$	**No**$_2$		134
Partial	**Yes**$_1$	**No**$_2$		15	**Yes**$_1$	**No**$_2$		39	**Yes**$_1$	**No**$_2$		63	**Yes**$_1$	**No**$_2$		87	**Yes**$_1$	**No**$_2$		111	**Yes**$_1$	**No**$_2$		135
None	**Yes**$_1$	**No**$_2$		16	**Yes**$_1$	**No**$_2$		40	**Yes**$_1$	**No**$_2$		64	**Yes**$_1$	**No**$_2$		88	**Yes**$_1$	**No**$_2$		112	**Yes**$_1$	**No**$_2$		136
Restoration Material																								
Amalgam	**Yes**$_1$	**No**$_2$		17	**Yes**$_1$	**No**$_2$		41	**Yes**$_1$	**No**$_2$		65	**Yes**$_1$	**No**$_2$		89	**Yes**$_1$	**No**$_2$		113	**Yes**$_1$	**No**$_2$		137
Glass ionomer	**Yes**$_1$	**No**$_2$		18	**Yes**$_1$	**No**$_2$		42	**Yes**$_1$	**No**$_2$		66	**Yes**$_1$	**No**$_2$		90	**Yes**$_1$	**No**$_2$		114	**Yes**$_1$	**No**$_2$		138
Composite	**Yes**$_1$	**No**$_2$		19	**Yes**$_1$	**No**$_2$		43	**Yes**$_1$	**No**$_2$		67	**Yes**$_1$	**No**$_2$		91	**Yes**$_1$	**No**$_2$		115	**Yes**$_1$	**No**$_2$		139
Preformed metal crown (conventional)	**Yes**$_1$	**No**$_2$		20	**Yes**$_1$	**No**$_2$		44	**Yes**$_1$	**No**$_2$		68	**Yes**$_1$	**No**$_2$		92	**Yes**$_1$	**No**$_2$		116	**Yes**$_1$	**No**$_2$		140
Preformed metal crown (Hall Technique)	**Yes**$_1$	**No**$_2$		21	**Yes**$_1$	**No**$_2$		45	**Yes**$_1$	**No**$_2$		69	**Yes**$_1$	**No**$_2$		93	**Yes**$_1$	**No**$_2$		117	**Yes**$_1$	**No**$_2$		141
Compomer	**Yes**$_1$	**No**$_2$		22	**Yes**$_1$	**No**$_2$		46	**Yes**$_1$	**No**$_2$		70	**Yes**$_1$	**No**$_2$		94	**Yes**$_1$	**No**$_2$		118	**Yes**$_1$	**No**$_2$		142
Resin modified GI	**Yes**$_1$	**No**$_2$		23	**Yes**$_1$	**No**$_2$		47	**Yes**$_1$	**No**$_2$		71	**Yes**$_1$	**No**$_2$		95	**Yes**$_1$	**No**$_2$		119	**Yes**$_1$	**No**$_2$		143
Sealant only	**Yes**$_1$	**No**$_2$		24	**Yes**$_1$	**No**$_2$		48	**Yes**$_1$	**No**$_2$		72	**Yes**$_1$	**No**$_2$		96	**Yes**$_1$	**No**$_2$		120	**Yes**$_1$	**No**$_2$		144
Sealant over restoration	**Yes**$_1$	**No**$_2$		25	**Yes**$_1$	**No**$_2$		49	**Yes**$_1$	**No**$_2$		73	**Yes**$_1$	**No**$_2$		97	**Yes**$_1$	**No**$_2$		121	**Yes**$_1$	**No**$_2$		145
Pulpotomy	**Yes**$_1$	**No**$_2$		26	**Yes**$_1$	**No**$_2$		50	**Yes**$_1$	**No**$_2$		74	**Yes**$_1$	**No**$_2$		98	**Yes**$_1$	**No**$_2$		122	**Yes**$_1$	**No**$_2$		146
Local Anaesthetic																								
Topical anaesthetic	**Yes**$_1$	**No**$_2$		27	**Yes**$_1$	**No**$_2$		51	**Yes**$_1$	**No**$_2$		75	**Yes**$_1$	**No**$_2$		99	**Yes**$_1$	**No**$_2$		123	**Yes**$_1$	**No**$_2$		147
Not attempted	**Yes**$_1$	**No**$_2$		28	**Yes**$_1$	**No**$_2$		52	**Yes**$_1$	**No**$_2$		76	**Yes**$_1$	**No**$_2$		100	**Yes**$_1$	**No**$_2$		124	**Yes**$_1$	**No**$_2$		148
Attempted and achieved	**Yes**$_1$	**No**$_2$		29	**Yes**$_1$	**No**$_2$		53	**Yes**$_1$	**No**$_2$		77	**Yes**$_1$	**No**$_2$		101	**Yes**$_1$	**No**$_2$		125	**Yes**$_1$	**No**$_2$		149
Attempted and not achieved	**Yes**$_1$	**No**$_2$		30	**Yes**$_1$	**No**$_2$		54	**Yes**$_1$	**No**$_2$		78	**Yes**$_1$	**No**$_2$		102	**Yes**$_1$	**No**$_2$		126	**Yes**$_1$	**No**$_2$		150
Other Procedures																								
Extraction	**Yes**$_1$	**No**$_2$		31	**Yes**$_1$	**No**$_2$		55	**Yes**$_1$	**No**$_2$		79	**Yes**$_1$	**No**$_2$		103	**Yes**$_1$	**No**$_2$		127	**Yes**$_1$	**No**$_2$		151
Lesion opened to make cleansable	**Yes**$_1$	**No**$_2$		32	**Yes**$_1$	**No**$_2$		56	**Yes**$_1$	**No**$_2$		80	**Yes**$_1$	**No**$_2$		104	**Yes**$_1$	**No**$_2$		128	**Yes**$_1$	**No**$_2$		152
Was tooth treated according to randomized arm of clinical protocol	**Yes**$_1$	**No**$_2$		33	**Yes**$_1$	**No**$_2$		57	**Yes**$_1$	**No**$_2$		81	**Yes**$_1$	**No**$_2$		105	**Yes**$_1$	**No**$_2$		129	**Yes**$_1$	**No**$_2$		153
How many surfaces managed operatively? (1-5 please state)				34				58				82				106				130				154

9

	Not at all										Very	
13. How satisfied were you with the visit?	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	10-11

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14. What was <u>your</u> estimation of the discomfort experienced by the child?

No apparent discomfort	.....	1
Very mild, almost trivial	.....	2
Mild, not significant	.....	3
Moderate, but child coped	.....	4
Significant and unacceptable	.....	5

12

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15. Please rate the child's behaviour during the treatment session:

The child refused the treatment: cried forcefully, fearful, evidence of extreme negativism. It was very difficult to make any progress. 1

The child appeared reluctant to listen, respond or to accept the treatment and had some evidence of negative attitude. Some progress was possible 2

The child was accepting of treatment but was cautious. The child was willing to comply with the dentist, but appeared to have some reservations. 3

Child was completely cooperative; he/she was interested in the dental procedure and even enjoyed the experience. 4

13

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16. Were there any difficulties providing treatment?

Yes	.....	1	**If yes (Answer 16a)**
No	.....	2	**If no (Go to question 17)**

14

a) If yes please explain: *(Please circle the number that applies).*

Compliance of child 1
Compliance of parent 2
Small mouth 3
Moisture control 4
Unable to deliver LA 5
Other clinical (please list) 6

.....

.....

Other (please list) 7

.....

..... 15

17. Did you use inhalation sedation/ relative analgesia during treatment? 16

Yes 1

No 2

---

18. Was the patient referred to a hospital or dental treatment service for a dental opinion and/or treatment?

Yes 1

No 2

If yes (Answer 19)
If no (Go to question 20)

17

---

19. If Yes, please state where and what the referral was for;

Where?;.....

.....

What was the referral for? .....

---

20. Did you prescribe any painkillers at this visit?

Yes 1

No 2

If yes (Answer 20a)
If no (Go to question 21)

18

a. Please write in:

Name of medication	Dose (state unit)	Dose frequency	No of days prescribed

---

21. Did you prescribe any antibiotics at this visit?

Yes 1

No 2

If yes (Answer 21a)
END

19

a. Please write in:

Name of Antibiotic	Dose (state unit)	Dose frequency	No of days prescribed

Please check that all the items in the CRF have been completed.

☐ **If you have completed an ICDAS charting (first treatment appointment and final study visit only) please attach it to the back of this CRF.**

☐ **If you have completed a Treatment Deviation Form, fax it or take a copy and post it back to NCTU in the prepaid envelope provided marked for the attention of the FiCTION Trial Manager.**

☐ **Please file this completed CRF with a copy of the Treatment Deviation Form (if applicable) in the patient's records.**

Please remember that the randomly allocated treatment arm is the philosophy under which all treatment should be given. Even if you have had to deviate from the randomly allocated treatment arm on this occasion you should return to it for the next visit if possible. If there is a request to deviate from the randomly allocated treatment arm at the next visit please complete a copy of the Treatment Deviation Form and fax it back to NCTU.

FiCTION
Fillings in Children's Teeth; Indicated Or Not

db cc pv va

Participant Study Number

Area | Site | Participant | Time 1

Screening ID Number

FIRST TREATMENT AND FINAL VISIT ONLY

ICDAS Recording Sheet

Upper Right / Upper Left

Surface	55	54	53	52	51	61	62	63	64	65
	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
M																
O																
D																
B																
L																
⌬																

Lower Right / Lower Left

Surface	85	84	83	82	81	71	72	73	74	75
	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
M																
O																
D																
B																
L																
⌬																

Restoration and Sealant Codes

0 = Not sealed or restored
1 = Sealant, partial
2 = Sealant, full
3 = Tooth coloured restoration
4 = Amalgam restoration
5 = Stainless steel crown
6 = Porcelain, gold, PFM crown or veneer
7 = Lost or broken restoration
8 = Temporary restoration

A 2-digit code should be used

Caries Codes

0 = Sound tooth surface
1 = First visual change in enamel
2 = Distinct visual change in enamel
3 = Enamel breakdown, no dentine visible
4 = Dentinal shadow (not cavitated into dentine)
5 = Distinct cavity with visible dentine
6 = Extensive distinct cavity with visible dentine

Missing Teeth

97 = Extracted due to caries
98 = Missing for other reason
99 = Unerupted

PARENT BASELINE QUESTIONNAIRE

About your child's teeth

BASELINE APPOINTMENT

Newcastle Clinical Trials Unit
Institute of Health and Society
4th Floor, William Leech Building,
Medical School, Framlington Place
Newcastle upon Tyne
NE2 4HH
☎ 0191 222 8620 / 3819
ISRCTN77044005

About these questions

In this booklet, you will find some questions about your child's teeth. Some are about your child's teeth in general and some questions are about particular aspects of your child's teeth. We also have some questions about your child's lifestyle.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is **an example** of how to answer if you are a man.

Are you

A man..... (1)

A woman..... 2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 1980

What is your date of birth?

1	9		0	4		8	0
D	D		M	M		Y	Y

Please answer **every question**, unless the instructions ask you to do something else. You may feel that you are being asked to answer the same questions several times, but there are important differences and we need to know how you feel about each.

Don't think too long about any question. What comes into your head first is probably better than a long thought-out answer. If you have problems answering any question, please write that problem beside the question.

Similar questions will be asked at each of your future visits.

Remember that your name does not appear anywhere on this booklet. Only the study team will know who answered the questions. We will not tell anyone else what you said.

Please now go to the next page

Thank you for helping us with our study. We are asking for your help so we may understand more about the best way to look after children's teeth.

The questions are **NOT** a test and there are **NO RIGHT OR WRONG ANSWERS**. We just want to know what you think. Please read each of the following questions carefully and circle the number for the answer that best describes your child.

First two questions about your child:

1. Is your child: (please circle the number that describes your child)

A boy 1

A girl 2

2. What is your child's date of birth?

(please write the date in the boxes below)

D	D	M	M	Y	Y

---

3. To which of the following ethnic groups does your child belong?

(Please circle the number that best describes your child)

White 1
Black.....2
Indian, Pakistani or Bangladeshi 3
Chinese 4
Mixed race 5
Other *(please specify)*.....6

Please now go to the next page

The next set of questions are about your child's teeth generally

4. How would you rate the health of your child's teeth, lips, jaws and mouth?

Excellent 0

Very good.....1

Good 2

Fair.....3

Poor 4

---

5. How much is your child's overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?

Not at all.....0

Very little 1

Some.....2

A lot.....3

Very much.....4

The next set of questions are about specific aspects of your child's teeth

Please now go to the next page

The following questions ask about things your children may experience due to the condition of their teeth, lips, mouth and jaws.

6. During the last 3 months, how often has your child:

a) Had pain in the teeth, lips, jaw or mouth?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

b) Had bleeding gums?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

c) Had bad breath?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

d) Had food caught between the teeth?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

e) Breathed through the mouth?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

f) Had trouble sleeping?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

g) Had difficulty biting or chewing firm foods?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

h) Had difficulty drinking or eating hot or cold foods?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

i) Been irritable or frustrated?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

j) Worried that he/she is not as healthy as other people?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

k) Worried that he/she is different from other people?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

l) Acted shy or embarrassed?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

m) Not wanted or been unable to spend time with other children?

☐ Never ☐ Once or twice ☐ Sometimes ☐ Often ☐ Every day or almost every day ☐ Don't know

n) Not wanted to speak or read out loud in class?

☐ Never ☐ Once or twice ☐ Sometimes ☐ Often ☐ Every day or almost every day ☐ Don't know

o) Not wanted to talk to other children?

☐ Never ☐ Once or twice ☐ Sometimes ☐ Often ☐ Every day or almost every day ☐ Don't know

p) Been asked questions by other children about his/her teeth, lips, mouth or jaws?

☐ Never ☐ Once or twice ☐ Sometimes ☐ Often ☐ Every day or almost every day ☐ Don't know

7. Michigan Oral-Health-Related Quality of Life Questionnaire Parent Version

Please, tell me for each of the following statements how much you agree with it. Please circle your answer on the 5 point answer scale ranging from 1 = "disagree strongly" and 5 = "agree strongly".

Statement	Disagree strongly				Agree strongly
a) My child has a toothache or pain currently.	1	2	3	4	5
b) My child's teeth hurt when he/she eats/ drinks something hot or cold.	1	2	3	4	5
c) My child's teeth hurt when he/she eats/ drinks something sweet.	1	2	3	4	5
d) My child's teeth hurt when he/she bites/ chews.	1	2	3	4	5
e) My child' has pain when he/she opens his/her mouth wide.	1	2	3	4	5
f) My child sometimes wakes up at night with a tooth ache.	1	2	3	4	5
g) My child sometimes has a tooth ache at school.	1	2	3	4	5
h) My child sometimes misses a day of school because of a toothache.	1	2	3	4	5
i) My child has a nice smile.	1	2	3	4	5
j) My child is happy with his / her teeth.	1	2	3	4	5
k) My child sometimes complains about his / her teeth.	1	2	3	4	5

8. When did you fill in this questionnaire?

(please write the date in the boxes below)

D	D	M	M	Y	Y

Please now go to the next page

Please hand this booklet back to a member of staff.

You will need to answer the rest of the questions at the treatment visit.

The following question should be filled out **before** your child has had their treatment.

9. Before seeing the dentist today, do you think your child was?

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

These next questions are about your child's behavior.

10. Is your child:

		Never	Sometimes	Often
a.	Biting things off with their back teeth instead of their front teeth?	1	2	3
b.	Putting sweets away just after starting eating?	1	2	3
c.	Starting to cry during meals?	1	2	3
d.	Having problems with brushing upper teeth?	1	2	3
e.	Having problems with brushing lower teeth?	1	2	3
f.	Having problems chewing?	1	2	3
g.	Chewing at one side?	1	2	3
h.	Suddenly reaching for his/her cheek while eating?	1	2	3

Please now go to the next page

You will need to fill in the rest of the questions after your child has had their treatment. Please wait until after they have had their treatment before completing question 11 onwards.

The following questions should be filled out **after** your child has had their treatment.

11. Thinking about being at the dentist today, do you think your child was?

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

---

12. Thinking about being at the dentist today how do you think your child found the treatment?

Not at all painful 1

A little painful.....2

Somewhat painful.....3

Painful.....4

Very painful.....5

---

13. Who completed this questionnaire?
(please circle the number that describes you)

Mother.....1

Father.....2

Other (please state who)

.....3

Please now go to the next page

14. Did you attend the appointment with your child?

Yes..... 1 **Answer Q15**

No ..... 2 **Go to Q16**

---

15. Where were you during the visit?
(please circle the number that describes where you were)

In the surgery with my child …….1

In the waiting room ……2

---

16. When did you fill in this questionnaire?
(please write the date in the boxes below)

D	D	M	M	Y	Y

Please make sure you have answered **ALL** questions.

Please hand this booklet back to a member of staff.

THANK YOU
FOR YOUR HELP

PARENT SUBSEQUENT APPOINTMENT QUESTIONNAIRE

db cc pv va

CONFIDENTIAL

Participant Study Number

Area Site Participant

1 - 8

Screening ID Number

9 - 16

FiCTION

Fillings in Children's Teeth; Indicated Or Not

About your child's teeth

Practice staff only

SCHEDULED/RECALL APPOINTMENT.....2

EMERGENCY /UNSCHEDULED APPOINTMENT.....3

17

Newcastle Clinical Trials Unit
Institute of Health and Society
4th Floor, William Leech Building,
Medical School, Framlington Place
Newcastle upon Tyne
NE2 4HH
0191 222 8620 / 3819
ISRCTN77044005

About these questions

In this booklet, you will find some questions about your child's teeth. Some are about your child's teeth in general and some about your child's teeth in particular. We also have some questions about your child's lifestyle.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is **an example** of how to answer if you are a man.

Are you

A man..... (1)

A woman.....2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 1980

What is your date of birth?

1	9		0	4		8	0
D	D		M	M		Y	Y

Please answer **every question**, unless the instructions ask you to do something else. Some of the questions may seem to be asking much the same thing, but there are important differences and we need to know how you feel about each.

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Similar questions will be asked at each of your future visits.

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Please now go to the next page

Thank-you for helping us with our study. We are asking for your help so we may understand more about the best way to look after children's teeth.

The questions are **NOT** a test and there are **NO RIGHT OR WRONG ANSWERS**. We just want to know what you think. Please read each of the following questions carefully and circle the number for the answer that best describes your child.

The following questions should be filled out **before** your child has had their treatment.

1. Before seeing the dentist today, do you think your child was?

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

Please now go to the next page

These next questions are about your child's behavior.

2. Is your child:

		Never	Sometimes	Often	
a.	Biting things off with their back teeth instead of their front teeth?	1	2	3	19
b.	Putting sweets away just after starting eating?	1	2	3	20
c.	Starting to cry during meals?	1	2	3	21
d.	Having problems with brushing upper teeth?	1	2	3	22
e.	Having problems with brushing lower teeth?	1	2	3	23
f.	Having problems chewing?	1	2	3	24
g.	Chewing at one side?	1	2	3	25
h.	Suddenly reaching for his/her cheek while eating?	1	2	3	26

Please now go to the next page

These next questions refer to pain from tooth decay since the child's last visit to this dentist.

3. Has your Child had toothache since the last visit to the dentist?

Yes .....1† **Answer Q4**

No .....2† **Go to Q17** 27

4. Was your child absent from school because of the pain arising from tooth decay? (Please circle response)

Yes .....1† **Answer Q5**

No.....2 **Go to Q6**

Not applicable because:

My child is preschool age……..…3

Pain occurred in school holidays……..4† 28

5. How long was your child absent from school because of the pain? (Please circle response)

Less than one day 1

One day ..... 2†

Two days 3

Three days 4

Four days 5

Five days …… 6

More than five days† 7 29

Please now go to the next page

6. Did you, or anyone else, need to take any time off paid work to look after your child?

Yes .....1† **Answer Q7**

No .....2† **Go to Q8**

30

---

7. How much time was taken off paid work?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days 6

More than five days† 7

31

---

8. Did you need to arrange any additional paid child-care for your child as a result of the pain arising from tooth decay?

Yes .....1† **Answer Q9**

No .....2† **Go to Q10**

32

Please now go to next page

9. How much extra paid child-care did you have to arrange for your child?

Less than one day	1	
One day	2	†
Two days	3	
Three days	4	
Four days	5	
Five days	6	
More than five days†	7	33

---

10. Did your child need any pain-killing medicine (which was not prescribed) because of the pain arising from tooth decay? (if yes, please tell us what kind it was)

Yes (please state below).....1	**Answer Q11**	
…….....		
No 2	**Go to Q12**	34

Please now go to next page

11. For how long did your child need the pain-killing medicine?

Less than one day	1	
One day	2	
Two days	3	
Three days	4	
Four days	5	
Five days	6	
More than five days	7	35

12. Were <u>you</u> unable to participate in your usual activities outside of work because of your child's tooth pain?

Yes	1	**Answer Q13**
No	2	**Go to Q15** 36

13. If you were unable to participate in your usual activities outside of work how long was this for?

Less than one day	1	
One day	2	
Two days	3	
Three days	4	
Four days	5	
Five days	6	
More than five days	7	37

Please now go to the next page

14. If you were unable to participate in your usual activities what would you have been doing during this time

Housework 1

Voluntary work 2

Leisure time 3

Other (please specify).....4 38

---

15. Was your child unable to participate in their usual activities outside of school because of their tooth pain?

Yes .....1† **Answer Q16**

No .....2 **Go to Next Page** 39

---

16. If your child was unable to participate in their usual activities outside of school how long was this for?

Less than one day 1

One day ..... 2 †

Two days 3

Three days 4

Four days 5

Five days 6

More than five days† 7

Not applicable 8 40

Please now go to the next page

You will need to answer the rest of the questions after your child has had their treatment. Please wait until after they have had their treatment before completing Question 17 onwards.

The following questions must be filled out **after** your child has had their treatment.

17. Thinking about being at the dentist today, do you think your child was?

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5 41

---

18. Thinking about being at the dentist today how do you think your child found the treatment?

Not at all painful 1

A little painful.....2

Somewhat painful.....3

Painful 4

Very painful 5 42

---

19. Who completed this questionnaire? (*please circle the number that describes you*)

Mother.....1

Father.....2

Other (please state who)

.....3 43

---

20. Did you attend the appointment with your child?

Yes..... 1 **Answer Q21**

No ..... 2 **Go to Q22** 44

Please now go to the next page

21. Where were you during the visit?
(please circle the number that describes where you were)

In the surgery with my child ……. 1

In the waiting room ……. 2

45

---

22. When did you fill in this questionnaire?
(please write the date in the boxes below)

D	D	M	M	Y	Y

46 - 51

Please make sure you have answered **ALL** questions.

THANK YOU
FOR YOUR HELP

PARENT NON-ATTENDANCE / FINAL STUDY VISIT QUESTIONNAIRE

CONFIDENTIAL

Participant Study Number

Area	Site	Participant

Screening ID Number

FiCTION

Fillings in Children's Teeth; Indicated Or Not

About your child's teeth

PARENT SUBSEQUENT NON-ATTENDANCE /

FINAL NON-ATTENDANCE ASSESSMENT

Practice to delete as appropriate

Newcastle Clinical Trials Unit
Institute of Health and Society
1–2 Claremont Terrace
Newcastle University
Newcastle upon Tyne
NE2 4AE
☎ 0191 208 8620 / 3819
ISRCTN77044005

About these questions

In this booklet, you will find some questions about your child's teeth. Some are about your child's teeth in general and some questions are about particular aspects of your child's teeth. We also have some questions about your child's lifestyle.

Please work through the booklet, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is **an example** of how to answer if you are a man.

Are you

A man..... (1)

A woman..... 2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 1980

What is your date of birth?

1	9		0	4		8	0
D	D		M	M		Y	Y

Please answer **every question**, unless the instructions ask you to do something else. You may feel that you are being asked to answer the same questions several times, but there are important differences and we need to know how you feel about each.

Don't think too long about any question. What comes into your head first is probably better than a long thought-out answer. If you have problems answering any question, please write that problem beside the question.

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Please now go to the next page

Thank you for helping us with our study. We are asking for your help so we may understand more about the best way to look after children's teeth.

The questions are **NOT** a test and there are **NO RIGHT OR WRONG ANSWERS**. We just want to know what you think. Please read each of the following questions carefully and circle the number for the answer that best describes your child.

First two questions about your child:

1. Is your child: (please circle the number that describes your child)

A boy 1

A girl 2

2. What is your child's date of birth?

(please write the date in the boxes below)

D	D	M	M	Y	Y

Please now go to the next page

The next question is about your child's dentist appointments

Lots of people miss or have to cancel their appointments with the dentist for different reasons to do with their child, family or work. We think you have missed your child's last appointment and it would be helpful for our research if you could tell us why that was.

3. Which of these statements best applies to your child's last appointment?
Please circle one answer only

I wasn't' aware/I forgot that we had an appointment.	1
I didn't know what the appointment was for, so I didn't know if my child needed to attend or not.	2
I didn't think my child needed the appointment as they had no problem with their teeth.	3
I thought my child should attend the appointment but it was not at a convenient time.	4
I thought my child should attend the appointment but they didn't want to go.	5
I thought my child should attend the appointment but they were poorly.	6
I thought my child should attend the appointment but we were busy.	7
My child has attended an appointment with another dentist/ practice.	8

Other, please provide brief details:……

……..

Please now go to the next page

The next set of questions are about your child's teeth generally

4. How would you rate the health of your child's teeth, lips, jaws and mouth?

Excellent 0

Very good 1

Good.....2

Fair 3

Poor.....4

---

5. How much is your child's overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth?

Not at all 0

Very little.....1

Some 2

A lot 3

Very much 4

Please now go to the next page

The next set of questions are about specific aspects of your child's teeth

The following questions ask about things your children may experience due to the condition of their teeth, lips, mouth and jaws.

6. During the last 3 months, how often has your child:

a) Had pain in the teeth, lips, jaw or mouth?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

b) Had bleeding gums?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

c) Had bad breath?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

d) Had food caught between the teeth?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

e) Breathed through the mouth?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

f) Had trouble sleeping?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

g) Had difficulty biting or chewing firm foods?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

h) Had difficulty drinking or eating hot or cold foods?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

i) Been irritable or frustrated?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

j) Worried that he/she is not as healthy as other people?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

k) Worried that he/she is different from other people?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

l) Acted shy or embarrassed?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

m) Not wanted or been unable to spend time with other children?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

n) Not wanted to speak or read out loud in class?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

o) Not wanted to talk to other children?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

p) Been asked questions by other children about his/her teeth, lips, mouth or jaws?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

7. Is your child:

		Never	Sometimes	Often
a.	Biting things off with their back teeth instead of their front teeth?	1	2	3
b.	Putting sweets away just after starting eating?	1	2	3
c.	Starting to cry during meals?	1	2	3
d.	Having problems with brushing upper teeth?	1	2	3
e.	Having problems with brushing lower teeth?	1	2	3
f.	Having problems chewing?	1	2	3
g.	Chewing at one side?	1	2	3
h.	Suddenly reaching for his/her cheek while eating?	1	2	3

Please now go to the next page

These next questions refer to pain from tooth decay <u>since</u> the child's last visit to this dentist.

If your child has <u>not</u> had toothache since the last visit to this dentist, please miss out Questions 8 to 20.

8. As well as you can remember was your child absent from school because of the pain arising from tooth decay? (Please circle response)

Yes 1

Answer Q9

No 2

Not applicable because:

My child is preschool age……..3

Pain occurred in school holidays……..…..4

Don't remember……..…5

Go to Q10

---

9. How long was your child absent from school because of the pain? (Please circle response)

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days …… 6

More than five days 7

Don't remember ……..…… 8

Please now go to the next page

10. Did you, or anyone else, need to take any time off paid work to look after your child?

Yes .....1╢ **Answer Q11**

No 2

Don't remember ……..…3 **Go to Q12**

---

11. How much time was taken off paid work?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days ……. 6

More than five days╢ 7

Don't remember ……... 8

---

12. Did you need to arrange any additional paid child-care for your child as a result of the pain arising from tooth decay?

Yes .....1╢ **Answer Q13**

No 2

Don't remember ……..……..3 **Go to Q14**

Please now go to next page

13. How much extra paid child-care did you have to arrange for your child?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days 6

More than five days 7

Don't remember 8

---

14. Did your child need any pain-killing medicine (which was not prescribed) because of the pain arising from tooth decay? (if yes, please tell us what kind it was)

Yes (please state below).....1 **Answer Q15**

…….....

No .....2 **Go to Q16**

Don't remember ……..…..……3

Please now go to next page

15. For how long did your child need the pain-killing medicine?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days 6

More than five days 7

Don't remember 8

---

16. Were <u>you</u> unable to participate in your usual activities outside of work because of your child's tooth pain?

Yes .....1 **Go to Q17**

No .....2 **Go to Q18**

Don't remember 3

Please now go to the next page

17. If you were unable to participate in your usual activities outside of work, how long was this for?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days 6

More than five days 7

Not applicable 8

Don't remember 9

---

18. If you were unable to participate in your usual activities, what would you have been doing during this time?

Housework.....1

Voluntary work.....2

Leisure time.....3

Other (please specify).....4

Don't remember.....5

Please now go to the next page

19. Was your child unable to participate in their usual activities outside of school because of their tooth pain?

Yes .....1 **Answer Q20**

No 2

Don't remember 3

---

20. If your child was unable to participate in their usual activities outside of school how long was this for?

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days 6

More than five days 7

Not applicable 8

Don't remember 5

---

21. Who completed this questionnaire? (*please circle the number that describes you*)

Mother.....1

Father.....2

Other (please state who)

.....3

Please now go to the next page

22. When did you fill in this questionnaire?

(please write the date in the boxes below)

D	D	M	M	Y	Y

Please make sure you have answered **ALL** questions.

THANK YOU
FOR YOUR HELP

PARENT FINAL STUDY VISIT QUESTIONNAIRE

Participant Study Number

Area	Site	Participant

CONFIDENTIAL

Screening ID Number

FiCTION

Fillings in Children's Teeth; Indicated Or Not

About your child's teeth

FINAL ASSESSMENT……4

Newcastle Clinical Trials Unit
Institute of Health and Society
1–2 Claremont Terrace
Newcastle University
Newcastle upon Tyne
NE2 4AE
☎ 0191 208 8620 / 3819
ISRCTN77044005

About these questions

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Are you

A man..... (1)

A woman..... 2

Sometimes, you need to write a number in a box. Here is **an example** of how you would answer if you were born on 19 April 1980

What is your date of birth?

1	9		0	4		8	0
D	D		M	M		Y	Y

Please answer **every question**, unless the instructions ask you to do something else. You may feel that you are being asked to answer the same questions several times, but there are important differences and we need to know how you feel about each.

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Please now go to the next page

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The questions are **NOT** a test and there are **NO RIGHT OR WRONG ANSWERS**. We just want to know what you think. Please read each of the following questions carefully and circle the number for the answer that best describes your child.

First two questions about your child:

1. Is your child: (please circle the number that describes your child)

A boy 1

A girl 2

2. What is your child's date of birth?

(please write the date in the boxes below)

D	D	M	M	Y	Y

Please now go to the next page

The next set of questions are about your child's teeth generally

3. How would you rate the health of your child's teeth, lips, jaws and mouth? (Please circle response)

Excellent 0

Very good.....1

Good 2

Fair.....3

Poor 4

---

4. How much is your child's overall wellbeing affected by the condition of his/her teeth, lips, jaws or mouth? (Please circle response)

Not at all.....0

Very little 1

Some.....2

A lot.....3

Very much.....4

Please now go to the next page

The next set of questions are about specific aspects of your child's teeth

The following questions ask about things your children may experience due to the condition of their teeth, lips, mouth and jaws.

5. During the last 3 months, how often has your child: (Please circle responses)

a) Had pain in the teeth, lips, jaw or mouth?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

b) Had bleeding gums?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

c) Had bad breath?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

d) Had food caught between the teeth?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

e) Breathed through the mouth?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

f) Had trouble sleeping?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

g) Had difficulty biting or chewing firm foods?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

h) Had difficulty drinking or eating hot or cold foods?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

i) Been irritable or frustrated?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

j) Worried that he/she is not as healthy as other people?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

k) Worried that he/she is different from other people?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

l) Acted shy or embarrassed?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

m) Not wanted or been unable to spend time with other children?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

n) Not wanted to speak or read out loud in class?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

o) Not wanted to talk to other children?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

p) Been asked questions by other children about his/her teeth, lips, mouth or jaws?

☐	☐	☐	☐	☐	☐
Never	Once or twice	Sometimes	Often	Every day or almost every day	Don't know

6. Michigan Oral-Health-Related Quality of Life Questionnaire Parent Version

Please, tell me for each of the following statements how much you agree with it. Please circle your answer on the 5 point answer scale ranging from 1 = "disagree strongly" and 5 = "agree strongly".

Statement	Disagree strongly				Agree strongly
a) My child has a toothache or pain currently.	1	2	3	4	5
b) My child's teeth hurt when he/she eats/ drinks something hot or cold.	1	2	3	4	5
c) My child's teeth hurt when he/she eats/ drinks something sweet.	1	2	3	4	5
d) My child's teeth hurt when he/she bites/ chews.	1	2	3	4	5
e) My child' has pain when he/she opens his/her mouth wide.	1	2	3	4	5
f) My child sometimes wakes up at night with a tooth ache.	1	2	3	4	5
g) My child sometimes has a tooth ache at school.	1	2	3	4	5
h) My child sometimes misses a day of school because of a toothache.	1	2	3	4	5
i) My child has a nice smile.	1	2	3	4	5
j) My child is happy with his / her teeth.	1	2	3	4	5
k) My child sometimes complains about his / her teeth.	1	2	3	4	5

7. Before coming to the dentists today, do you think your child was?
(Please circle response)

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

.....

8. Is your child: (Please circle response)

		Never	Sometimes	Often
a.	Biting things off with their back teeth instead of their front teeth?	1	2	3
b.	Putting sweets away just after starting eating?	1	2	3
c.	Starting to cry during meals?	1	2	3
d.	Having problems with brushing upper teeth?	1	2	3
e.	Having problems with brushing lower teeth?	1	2	3
f.	Having problems chewing?	1	2	3
g.	Chewing at one side?	1	2	3
h.	Suddenly reaching for his/her cheek while eating?	1	2	3

Please now go to the next page

These next questions refer to pain from tooth decay since the child's last visit to this dentist.

9. Has your Child had toothache since the last visit to the dentist?
(Please circle response)

Yes .....1 → **Answer Q10**

No .....2 → **Go to Q22**

27

10. Was your child absent from school because of the pain arising from tooth decay?
(Please circle response)

Yes .....1 → **Answer Q11**

No 2

Not applicable because:

My child is preschool age……..3

Pain occurred in school holidays……..…..4

Don't remember…….....….5

→ **Go to Q12**

---

11. How long was your child absent from school because of the pain?
(Please circle response)

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days …… 6

More than five days 7

Don't remember ……..…… 8

Please now go to the next page

12. Did you, or anyone else, need to take any time off paid work to look after your child? (Please circle response)

Yes .....1 → **Answer Q13**

No 2

Don't remember ……3 → **Go to Q14**

---

13. How much time was taken off paid work? (Please circle response)

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days ……. 6

More than five days 7

Don't remember ……... 8

---

14. Did you need to arrange any additional paid child-care for your child as a result of the pain arising from tooth decay? (Please circle response)

Yes .....1 → **Answer Q15**

No 2

Don't remember ……..…….3 → **Go to Q16**

Please now go to next page

15. How much extra paid child-care did you have to arrange for your child?
(Please circle response)

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days 6

More than five days 7

Don't remember 8

---

16. Did your child need any pain-killing medicine (which was not prescribed) because of the pain arising from tooth decay? (if yes, please tell us what kind it was)
(Please circle response)

Yes (please state below).....1 **Answer Q17**

…….....

No .....2 **Go to Q18**

Don't remember ……..…..……3

Please now go to next page

17. For how long did your child need the pain-killing medicine? (Please circle response)

Less than one day	1
One day	2
Two days	3
Three days	4
Four days	5
Five days	6
More than five days	7
Don't remember	8

---

18. Were <u>you</u> unable to participate in your usual activities outside of work because of your child's tooth pain? (Please circle response)

Yes 1	**Answer Q19**
No 2	**Go to Q21**
Don't remember 3	

Please now go to the next page

19. If you were unable to participate in your usual activities outside of work how long was this for? (Please circle response)

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days 6

More than five days 7

Not applicable 8

Don't remember 9

---

20. If you were unable to participate in your usual activities what would you have been doing during this time? (Please circle response)

Housework 1

Voluntary work 2

Leisure time 3

Other (please specify).....4

Don't remember.....5

Please now go to the next page

21. Was your child unable to participate in their usual activities outside of school because of their tooth pain? (Please circle response)

Yes .....1 → **Answer Q22**

No .....2 → **Go To Q23**

Don't remember……...……3

---

22. If your child was unable to participate in their usual activities outside of school how long was this for? (Please circle response)

Less than one day 1

One day 2

Two days 3

Three days 4

Four days 5

Five days …… 6

More than five days 7

Not applicable 8

Don't remember …… 5

Please now go to the next page

You will be asked to answer the rest of the questions after your child has had their examination. Please wait until after they have had their examination before completing Question 23 onwards.

The following questions must be filled out **after** your child has had their examination.

23. Thinking about being at the dentist today, do you think your child was?
(Please circle response)

Not at all worried 1

Very slightly worried 2

Fairly worried 3

Quite worried.....4

Very worried.....5

41

---

24. Did your child receive treatment today? (please circle response)

Yes..... 1 **Answer Q25**

No ..... 2 **Go to Q26**

---

25. Thinking about being at the dentist today how do you think your child found the treatment? (Please circle response)

Not at all painful 1

A little painful.....2

Somewhat painful.....3

Painful.....4

Very painful.....5

---

26. Who completed this questionnaire? (please circle the number that describes you)
(Please circle response)

Mother.....1

Father.....2

Other (please state who)

.....3

Please now go to the next page.

27. Where were you during the visit? (please circle response)

In the surgery with my child ……. 1

In the waiting room ……. 2

---

28. When did you fill in this questionnaire?

(please write the date in the boxes below)

D	D	M	M	Y	Y

Please make sure you have answered **ALL** questions.

THANK YOU
FOR YOUR HELP

Child Baseline & Subsequent Appointment Questionnaire

Questions about your teeth

Practice staff only

BASELINE APPOINTMENT 1
SCHEDULED APPOINTMENT.....2
UNSCHEDULED APPOINTMENT.....3
FINAL.....4

Newcastle Clinical Trials Unit
Institute of Health and Society
4th Floor, William Leech Building,
Medical School, Framlington Place
Newcastle upon Tyne
NE2 4HH
☎ 0191 222 8620 / 3819
ISRCTN77044005

FiCTION
Fillings in Children's Teeth; Indicated Or Not

About these questions – instructions to parents

In this booklet, you will find some questions about your child's teeth. We would be very grateful if you could read the questions to your child and help them to mark their answer on the form. Some of the questions may seem to be asking the same thing but each question tells us about something slightly different that we would like to find out.

Please work through the booklet with your child, answering each question as you go. At the start of each set of questions, there are some instructions on how to answer those questions. Most of the questions can be answered by simply circling a number. Here is **an example** of how to answer if your child is a boy.

Are you

A boy ..... (1)

A girl 2

Please answer **every question**, unless the instructions tell you to do something else.

Your child doesn't need to think too long about any question. What comes into their head first is probably better than a long thought-out answer. If there are any problems with answering any question, please write that problem beside the question.

Similar questions will be asked at each of your future visits.

Remember that neither your name nor your child's name will appear anywhere on this booklet. Only the study team will know who answered the questions. We will not tell anyone else what was said.

Please now go to the next page.

These questions need to be read out and completed with the help of a parent

Thanks for agreeing to help us with our study! This study is being done so we will understand more about the best way to care for your teeth. **PLEASE REMEMBER:**

- This is **not a test** and there are no right or wrong answers
- Just tell us what you think

Some questions about you

1. Are you:

Please circle which best describes you

A boy..... 1
A girl..... 2

---

2. How old are you?

Please write how many years old you are in the box provided. For example if you are five years old, please write 5 in the box provided

		years

Please now go to the next page.

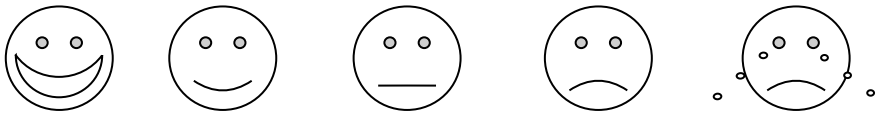
3. For these next questions I would like you to tell me how relaxed or worried you get about going to the dentist and what happens at the dentist.

   To show me how relaxed or worried you are, please circle the face that shows best how you feel. For example, if you were fairly worried you would circle the middle picture as shown below.

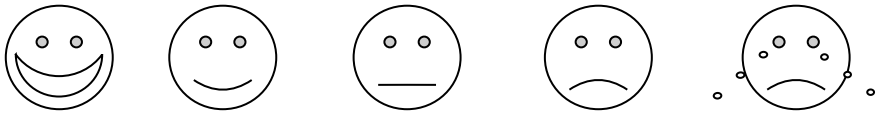
How do you feel about:

a) going to the dentist generally?

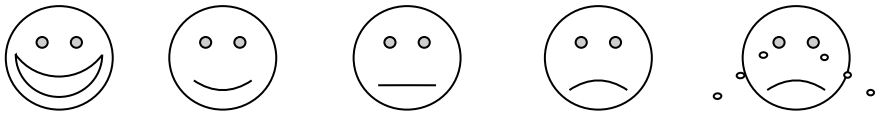
b) having your teeth looked at?



c) having your teeth scraped and polished?

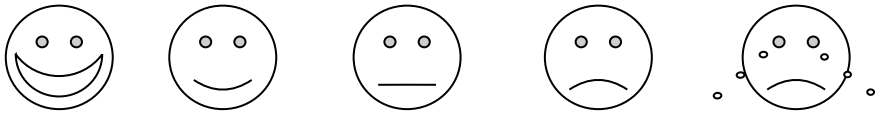


d) having an injection in your gum?



e) having a filling?

f) having a tooth taken out?



Please now go to the next page.

4. Before you saw the dentist today, were you?

(Please ask child to circle the face that describes how **worried** they were)

Not worried

1

A little worried

2

Very worried

3

---

5. When did you answer these questions?

(Please write the date in the boxes below)

D	D	M	M	Y	Y

Please now go to the next page.

Please now give the questionnaire to a member of staff at the dental practice. You will be asked to answer the remaining questions after seeing the dentist for treatment.

These questions must be filled in <u>after</u> you have had your treatment at the dentist.

We'd like you to tell us about how it felt at the dentist's today.

6 Thinking about your visit to the dentist today, were you?

(Please ask child to circle the face that describes how **worried** they were)

Not worried

1

A little worried

2

Very worried

3

---

7 Thinking about being at the dentist today, did it?

(*Please ask child to circle the face that describes **the visit)***

Not hurt at all

1

Hurt a little

2

Hurt a lot

3

---

8 Who helped you to answer your questions today?

Mother..... 1

Father..... 2

Other (please state who)

..... 3

Please now go to the next page.

9 When did you answer these questions?

(Please write the date in the boxes below)

D	D	M	M	Y	Y

You've done it! Well done on answering all our questions!

Please now give the questionnaire to a member of staff at the dental practice

CHILD NON-ATTENDANCE / FINAL STUDY VISIT QUESTIONNAIRE

Participant Study Number

Area		Site		Participant			

1 - 8

db cc pv va

CONFIDENTIAL

Screening ID Number

9 - 16

Questions about your teeth

CHILD NON-ATTENDANCE/FINAL ASSESSMENT

Practice to delete as appropriate

Newcastle Clinical Trials Unit
Institute of Health and Society
1-2 Claremont Place
Newcastle University
Newcastle upon Tyne
NE2 4AE
☎ 0191 208 8620 / 3819
ISRCTN77044005

FiCTION
Fillings in Children's Teeth; Indicated Or Not

17

About these questions – instructions to parents

In this booklet, you will find some questions about your child's teeth. We would be very grateful if you could read the questions to your child and help them to mark their answer on the form. Some of the questions may seem to be asking the same thing but each question tells us about something slightly different that we would like to find out.

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Are you

A boy ..... (1)

A girl 2

Please answer **every question**, unless the instructions tell you to do something else.

Your child doesn't need to think too long about any question. What comes into their head first is probably better than a long thought-out answer. If there are any problems with answering any question, please write that problem beside the question.

Similar questions will be asked at each of your future visits.

Remember that neither your name nor your child's name will appear anywhere on this booklet. Only the study team will know who answered the questions. We will not tell anyone else what was said.

Please now go to the next page.

These questions need to be read out and completed with the help of a parent

Thanks for agreeing to help us with our study! This study is being done so we will understand more about the best way to care for your teeth. **PLEASE REMEMBER:**

- This is **not a test** and there are no right or wrong answers
- Just tell us what you think

Some questions about you

1. Are you:

Please circle which best describes you

A boy 1
A girl 2 18

---

2. How old are you?

Please write how many years old you are in the box provided. For example if you are five years old, please write 5 in the box provided

		years 19 - 20

Please now go to the next page.

3. For these next questions I would like you to tell me how relaxed or worried you get about going to the dentist and what happens at the dentist.

   To show me how relaxed or worried you are, please circle the face that shows best how you feel. For example, if you were fairly worried you would circle the middle picture as shown below.

How do you feel about:

a) going to the dentist generally? 21

b) having your teeth looked at? 22

c) having your teeth scraped and polished? 23

d) having an injection in your gum? 24

e) having a filling? 25

f) having a tooth taken out? 26

Please now go to the next page.

4 Who helped you to answer your questions today?

Mother..... 1
Father..... 2
Other (please state who)
..... 3

36

5 When did you answer these questions?

(Please write the date in the boxes below)

D	D	M	M	Y	Y

37 - 42

You've done it! Well done on answering all our questions!

TREATMENT DEVIATION FORM

FiCTION
Fillings in Children's Teeth; Indicated Or Not

Area	Site	Participant	
			1-8

Treatment Deviation Form

Please complete this form and then fax it back to the NCTU on 0191 208 8901 marked "For the attention of the FiCTION Trial Manager".

1. Date of treatment

D D	M M	Y Y	9-14

2. To which treatment arm was the patient randomised? *(Please circle the number that applies)*.

Conventional	.....	1
Biological	.....	2
Prevention Alone	.....	3

15

The final character in the patient ID number gives you the randomly selected treatment arm

3. Within which treatment arm was the patient's care conducted at this visit?

(Please circle all the numbers that apply).

Conventional	.....	1
Biological	.....	2
Prevention Alone	.....	3

16-18

4. Please tell us more about why the randomly allocated arm was not followed. *(Please circle the number that applies and then give more detail below).*

Parent / carer request	.....	1
Child request	.....	2
Other	.....	3

19

Please give brief details of why randomised arm was not followed:

.....

.....

.....

Please remember that the randomly allocated treatment arm is the philosophy under which all treatment should be given. Even if you have had to deviate from the randomly allocated treatment arm on this occasion you should return to it for the next visit if possible. If there is a request to deviate from the randomly allocated treatment arm at the next visit please complete a copy of this form and fax it back to NCTU.

PARTICIPANT WITHDRAWAL FORM

Site Participant

Participant Withdrawal Form

Please complete this form and then fax it back to the NCTU on 0191 208 8901 marked "For the attention of the FiCTION Trial Manager".

1. Date of Withdrawal

D D M M Y Y

2. Please tell us why the Participant has decided to withdraw from the study.

Although a participant is not obliged to give his/her reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the participant's rights.

(Please circle the number that applies and then give more detail below).

Moving Away (and can't be accommodated in another FiCTION practice)	1
Study Fatigue (eg. too many appointments, too much paperwork)	2
Medical Reason (eg. medically compromised, hospital appointments)	3
Dental Reason (eg. traumatic event, GA, co-operation/compliance, unhappy with allocated arm)	4
Consent Issue (eg can't maintain on-going consent)	5
Personal Reason	6
Other (please state below)	7
No Reason Given	8
Practice Withdrawn [For NCTU office only]	9

For each category circled, where appropriate please give further details of why participant has decided to withdraw from the study:

.....

.....

.....

.....

Please inform the participant that we will still store their data collected up until point of withdrawal unless they specifically ask us not to by formally withdrawing their consent. If they decided to withdraw their consent, we would destroy all of the data held by us and from then on any anonymised data collected from them would not be included in the analyses we perform as part of this study.

DEMOGRAPHIC QUESTIONNAIRE - DENTAL PRACTICE STAFF

FiCTION: Filling Children's Teeth: Indicated Or Not?

What do dentists and dental practice team members think of the three treatment strategies for dental caries in children?

Participant Questionnaire

Qualitative study participant identification number:

☐☐☐

Job title _____

Year of qualification _____

Gender *(please circle)*: male / female

Do you have previous research experience? *(please circle all that apply and provide details if you answer 'yes' for any option)*:

- Yes – as a clinician recruiting patients and performing an intervention

*Details:*_____

- Yes – as a Principal Investigator of a study

*Details:*_____

- Yes – as a participant in a clinical trial

*Details:*_____

- No

For dental nurses only:

How long have you worked as a dental nurse? _____

Have you undertaken further training relevant to children's dentistry? *(please circle all that apply and provide details of any other relevant training)*:

- Yes – the extended training certificate in varnish application
- Yes – the extended training certificate in sedation
- Yes – the extended training certificate in radiology

- Yes – the extended training certificate in special needs
- Yes – the extended training certificate in impression taking
- Yes – the extended training certificate in orthodontic support
- Yes – the extended training certificate in oral hygiene instruction
- No

Details of any other relevant training_____

_____

For hygienists/therapists only:

Have you undertaken further training in children's dentistry? *(please circle and provide details if you answer 'yes')*:

- Yes – specific paediatric dentistry Continuous Professional Development courses
- Yes – other
- No

Details _____

_____

For dentists only:

What is your position? *(please circle)*

- Dental Practice Principal
- Dental Associate
- Community Dental Service Dentist

Have you undertaken further training or specialist training in children's dentistry? *(please circle and provide details if you answer 'yes')*:

- Yes – specific paediatric dentistry Continuous Professional Development courses
- Yes – extended training equivalent to be being a Dentist With Special Interest in paediatric dentistry
- Yes – a Senior House Office post in paediatric dentistry
- Yes – specialist training in paediatric dentistry
- No

Details _____

_____