GNOME: baseline measures form

DATE OF APPOINTMENT …………………..

Study ID number: [ ][ ][ ][ ][ ][ ][ ]

SPRAY NUMBER GIVEN: ………………………..

SWEEP PURE TONE AUDIOMETRY (BASELINE)

Performed at **25dB** in a ***quiet room***

✓ = pass   × = fail

	0.5 kHz	1 kHz	2 kHz	3kHz	4kHz
Right ear					
Left ear					

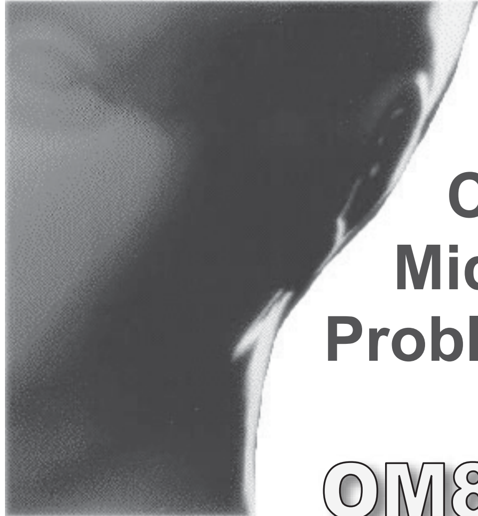
Comment: co-operative ☐ not co-operative☐

OPTIONAL

Appointment made with yourself or GP as part of *standard clinical care** ☐ Yes ☐ No

If yes, please specify the date(s) ……………………………………………………………………..

**This is your standard management (i.e. further watchful waiting, antibiotics, nose drops, referral or other treatment) for glue ear which you would do or advise to the patient if the trial were not taking place.*



Children's Middle Ear Problems

OM8-30

Parent* questionnaire

Study number

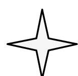
Baseline measures

**For parents or other regular caregivers*

Notes to parents on questionnaire completion

- ✦ For all questions, please tick **ONE** box opposite the description that *best fits* your child (even if you feel the description may not be absolutely accurate).

- ✦ Please be aware of the time period that the question is referring to, and answer for this time period – usually 3 months.



Thank you for completing this questionnaire;
all information given by you will be treated in confidence

OM8-30: Questionnaire

Section A: Global health

This question refers to the last 3 months

1.	***Taking everything into account, how would you say that your child's health has been?***	
	Very good	☐
	Good	☐
	Fair	☐
	Poor	☐

Section B: Respiratory symptoms

2.	***How often does he/she get colds?***	
	Once a week	☐
	Once every 2–3 weeks	☐
	Once every 1–3 months	☐
	Once every 4–6 months	☐
	Less often	☐
	Never	☐
	Not sure	☐

The remaining questions in this section refer to the last 3 months

3.	***How many times has he/she had a cough, cold or sore throat?***	
	Not at all	☐
	Once	☐
	2–3 times	☐
	4–5 times	☐
	6 or more times	☐

4. ***Has he/she breathed through his/her mouth?***	
Never	☐
Rarely	☐
Often	☐
Always	☐
Only when he/she has a cold	☐
Not sure	☐

5. ***Has he/she sounded as if he/she has a blocked nose?***	
Never	☐
Rarely	☐
Often	☐
Always	☐
Only when he/she has a cold	☐
Not sure	☐

6. ***Has he/she* usually *had a runny nose?***	
No	☐
Yes – clear	☐
Yes – purulent (yellowish or greenish)	☐
Only when he/she has a cold	☐
Not sure	☐

7. ***Has he/she snored or breathed heavily at night?***	
Never	☐
Rarely	☐
Often	☐
Always	☐
Only when he/she has a cold	☐
Not sure	☐

Section C: Ear problems

All questions in this section refer to the last 3 months

8. How many times has he/she had trouble with his/her ears?	
Not at all	☐
Once	☐
2–3 times	☐
4–5 times	☐
6 or more times	☐
9. How many ear infections has he/she had? **(i.e. severe pain in his/her ear, possibly with a temperature)**	
0	☐
1	☐
2–3	☐
4 or more	☐
Not sure	☐
10. How many times has he/she had an earache?	
0	☐
1	☐
2–3	☐
4 or more	☐
Not sure	☐

Section D: Reported hearing difficulties

All questions in this section refer to the last 3 months

11. How would you describe your child's hearing?	
Normal	☐
Slightly below normal	☐
Poor	☐
Very poor	☐
Not sure	☐
12. Has he/she misheard words when not looking at you?	
No	☐
Rarely	☐
Often	☐
Always	☐
Not sure	☐
13. Has he/she had difficulty hearing when with a group of people?	
No	☐
Rarely	☐
Often	☐
Always	☐
Not sure	☐
14. Has he/she asked for things to be repeated?	
No	☐
Rarely	☐
Often	☐
Always	☐
Not sure	☐

Section E: Behaviour

All questions in this section refer to the last 3 months

15. Sitting still (e.g. at meal time, story time or at other times) he/she…	
Is very active and does not sit still when necessary	☐
Can usually sit still when necessary	☐
Can sit still for a long period	☐
Is not active enough	☐
16. How long can he/she concentrate on a game or task you have given him/her to do?	
Up to 2 minutes	☐
Up to 5 minutes	☐
5–10 minutes	☐
10–15 minutes	☐
More than 15 minutes	☐
17. How often does he/she seek your attention unnecessarily? (e.g. asking for help for a task he/she can do themselves, demanding to be carried, demanding you to play with him/her, following you around)	
Less than once a month	☐
Once a month	☐
Once a week	☐
Once a day	☐
Two or three times a day	☐
18. How often does he/she whine or moan with little reason?	
Less than once a month	☐
Once a month	☐
Once a week	☐
Once a day	☐
Two or three times a day	☐

19.	***How often is he/she unhappy for no apparent reason?***
Less than once a month	☐
Once a month	☐
Once a week	☐
Once a day	☐
Two or three times a day	☐

20.	***When you take him/her out somewhere, does he/she do what you ask?***
Never	☐
Sometimes	☐
Often	☐
Always	☐

Section F: Speech and language

All questions in this section refer to the last 3 months

21.	***Has he/she mispronounced the beginnings or ends of words?***
No	☐
Rarely	☐
Often	☐
Always	☐
Not sure	☐

22.	***Has his/her speech been behind (less developed than) that of children of a similar age?***
No	☐
A little	☐
Moderately	☐
A lot	☐
Not sure	☐

23.	***When trying to tell you something, does he/she have poor articulation?*** **(e.g. unclear speech, missing out sounds, or producing the wrong sound)**
Yes	☐
No	☐

Section G: Sleep patterns

All questions in this section refer to the last 3 months

24. Do you think that the ear, nose or throat problems affect his/her sleep?	
Nearly always	☐
Sometimes	☐
Hardly ever	☐
25a. Would you say that your child is tired or listless during the day?	
Almost always	☐
Sometimes	☐
Never	☐
25b. If he/she is tired or listless during the day, do you think this happens at the same time as his/her ear, nose or throat condition?	
Almost always	☐
Sometimes	☐
Never	☐
Not applicable	☐

Section H: School prospects

This question refers to the last 3 months

26. Have you worried that your child's ear, nose or throat problem might slow down his/her progress at school?	
Often worried	☐
Sometimes worried	☐
Never worried	☐

Section I: Parent quality of life

All questions in this section refer to the last 3 months

27.	***Have your child's ear, nose or throat problems meant that you often feel tired?***	
	Yes	☐
	No	☐
28.	***Has your child needed more attention than other children?***	
	Yes	☐
	No	☐
29.	***Has your child been very demanding?***	
	Yes	☐
	No	☐
30.	***Has it taken a lot of energy to cope?***	
	Yes	☐
	No	☐
31.	***Would you agree that people wouldn't realise the effort involved until they had a child with ear or hearing problems?***	
	Yes	☐
	No	☐

GNOME: Costs to parents 1

To be done when taking baseline measures

Study ID number: ☐☐☐☐☐☐☐

1. Self-medication use for ear problems

Over the **past 12 months** have you self-treated your child (without coming to surgery) for an ear problem?

a) Using decongestant or antihistamine medicines/tablets? ☐ Yes ☐ No

If YES, How many occasions? ☐ 0–1 ☐ 1–2 ☐ 2–4 ☐ More than 4

b) Using a nose spray? ☐ Yes ☐ No

If YES, How many occasions? ☐ 0-1 ☐ 1–2 ☐ 2–4 ☐ More than 4

c) Using pain relieving medicine such as paracetamol, calpol, junior ibuprofen? ☐ Yes ☐ No

If YES, How many occasions? ☐ 0–1 ☐ 1–2 ☐ 2–4 ☐ More than 4

2. Activities

Has your child's teacher been concerned about ….

a) Your child not paying attention in class ☐ Yes ☐ No

If YES, how much
- ☐ Not at all
- ☐ Not very much
- ☐ A little
- ☐ Fairly concerned
- ☐ Very concerned

b) Your child's hearing in class ☐ Yes ☐ No

If YES, how much
- ☐ Not at all
- ☐ Not very much
- ☐ A little
- ☐ Fairly concerned
- ☐ Very concerned

Please turn over

c) Your child being dreamy in class ☐ Yes ☐ No

If YES, how much

- ☐ Not at all
- ☐ Not very much
- ☐ A little
- ☐ Fairly concerned
- ☐ Very concerned

d) Does your child enjoy swimming ☐ Yes ☐ No

If YES, how concerned are you that your child's ear problems/hearing have interfered with their swimming activities?

☐ Not at all ☐ Not very much ☐ A little ☐ Fairly concerned ☐ Very concerned

e) Does your child enjoy music Yes ☐ No ☐

If YES, how concerned are you that your child's ear problems/hearing have interfered with their music activities?

☐ Not at all ☐ Not very much ☐ A little ☐ Fairly concerned ☐ Very concerned

f) Does your child enjoy sports Yes ☐ No ☐

If YES, how concerned are you that your child's ear problems/hearing have interfered with their sports activities?

☐ Not at all ☐ Not very much ☐ A little ☐ Fairly concerned ☐ Very concerned

g) Does your child enjoy dancing ☐ Yes ☐ No

If YES, how concerned are you that your child's ear problems/hearing have interfered with their dancing activities?

☐ Not at all ☐ Not very much ☐ A little ☐ Fairly concerned ☐ Very concerned

h) How much time do you think your child has lost from school, nursery or playgroup over the past year because of ear problems

☐ Less than 1 week ☐ 1 week ☐ 2 weeks ☐ 3 weeks

☐ 4 weeks ☐ 5 weeks ☐ 6 weeks ☐ More than 6 weeks

i) Does your child suffer from:

Asthma	Yes ☐	No ☐
Eczema	Yes ☐	No ☐
Hay fever	Yes ☐	No ☐

3. Occupation

a) How do you describe your present occupation? …………………………………………………..

Is this part time? ☐ Yes ☐ No ☐ Not applicable

b) If you have a partner living in the household, how would you describe their present occupation?

………

Is this part time? ☐ Yes ☐ No ☐ Not applicable

c) How many occasions have you or a guardian of the child been unable to work or do your normal daily activities because of your child's ear problems over the last year?

☐ 0	☐1	☐2	☐ 3	☐ 4	☐ 5	☐ 6
☐ 7	☐ 8	☐9	☐10	☐11	☐ 12	☐More than 12

GNOME: adherence questionnaire

To be done 7 days after BASELINE MEASURES taken

Study ID number: | | | | | | | |

SPRAY NUMBER GIVEN: ……………………….

'Hello my name is …………….. the research nurse working on the research trial your child has just entered. Would it be OK to ask a few questions about your use of the nasal spray – it should only take a few minutes. If it's inconvenient at the moment I can call back at a more convenient time. The information you give is entirely confidential.

Just to check……………..'

1. Can you tell me the name of the nasal spray you were given as part of our study?

………

2. What is the reason for using the nasal spray?

………

3. Does your child still have the condition or problem that the nasal spray was given for?

………

If yes, the condition / problem has improved ☐ Yes ☐ No
the condition / problem has not changed ☐ Yes ☐ No
the condition / problem has got worse ☐ Yes ☐ No

4. Has your child started taking the nasal spray? ☐ Yes ☐ No

5. How many days has your child been taking it?..............................

6. How many times a day is your child taking it?...............................

Please turn over

7. How many squirts do you use into each nostril each time?...........................

8. How many times has your child missed taking the nasal spray?....................

9. How well do you think this spray is working for your child?

☐ Very well ☐ OK ☐ Not well

10. Have you any concerns or experienced any problems about your child taking this nasal spray?

a) The nasal spray has not worked / does not work ☐ Yes ☐ No

b) It gives my child unwanted effects (side-effects) ☐ Yes ☐ No

c) It is difficult to give to my child ☐ Yes ☐ No

d) I worry about the long term use of this spray ☐ Yes ☐ No

e) I am concerned this spray may be harmful ☐ Yes ☐ No

f) Any other problems………………………………………………………………………………………

………………………………………………………………………………………………………

11. Would you like more information about the nasal spray or study in general? ☐ Yes ☐ No

If yes, what?...

12. Have you experienced any difficulties with recording the symptom diary? ☐ Yes ☐ No

If yes, what?...

13. Do you think your child is taking the active nose spray? ☐ Yes ☐ No ☐ Don't know

14. If your child had not taken the spray would you have told me? Yes ☐ No ☐

FINALLY – do you have any comments you would like to add?………………………….……………

……

……

THANK YOU FOR YOUR TIME

and just to confirm your next appointment with me is on…………………..

GNOME: Health Economics Evaluation Form 1

To be done at time of taking BASELINE MEASURES by computer search

Study ID number: | | | | | | | |

In the previous 15 months

1. **All appointments for OM or OME (ear problems)**
   a) List the dates of appointments with GP: ………………………..……………………………
   b) List the dates of appointments with nurse: …………………….……………………...
   c) List the dates of appointments with health visitor: …………………..………………..
   d) List the dates of home visits: ……………………………………………….…………..
   e) List the dates of telephone consultations: with GP ....……………………………………
   with nurse …………………………………...
   f) List the dates of out of hours consultations: …………………………...……………………

2. **Referral for OM or OME (ear problems)**
   a) Date …………………………………
   b) Main reason ………………………………………………………………………...…
   …………………………………………………………………………………………………….
   c) To where? ☐ ENT ☐ Audiology ☐ Other
   please state ……………………..……

3. **Hospitalisation**
   a) Grommets / t-tubes / ventilation tubes: Yes / No Date(s) ……………………..
   b) Adenoidectomy: planned Yes / No Date …………………………
   done Yes / No Date …………………………

Please turn over

4. Treatment courses for OM or OME (ear problems)

a) Antibiotics:

Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….

b) Autoinflation   Yes / No   Date ……………………….

c) Decongestants and antihistamines:

Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….

d) Analgesics:

Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….
Date ……………….. name …………………………. dose ……………….. days ……….

5. Investigations for OM or OME (hearing problems)

e.g. blood tests / X-rays,

please give dates : ……………………………………………………………………………

………………………………………………………………………………………………
………………………………………………………………………………………………
………………………………………………………………………………………………