

AIRS: Initial Appointment Form



Study ID Number:

Date of Appointment:

Gender: Female Male

Age: years months

Patient's first name:	Patient's surname:
Postcode:	Telephone:
Address:	
Date of Birth:	

Q1. Was this child recruited from:

4-6 year old list (go to Q2) 7-11 year old list (go to Q3) GP/Nurse/HV referral (go to Q3)

Q2 Please ask which symptom(s) their child has had in the last 3 months:

	Yes	No		Yes	No
(a) A cold, cough or chesty infection	<input type="checkbox"/>	<input type="checkbox"/>	(h) Appears to be lip reading	<input type="checkbox"/>	<input type="checkbox"/>
(b) An earache	<input type="checkbox"/>	<input type="checkbox"/>	(i) Not doing as well at school as you or the teacher reasonably think	<input type="checkbox"/>	<input type="checkbox"/>
(c) Often mishears what is said	<input type="checkbox"/>	<input type="checkbox"/>	(j) Has noises in the ear or is dizzy	<input type="checkbox"/>	<input type="checkbox"/>
(d) Hearing loss is suspected by anyone	<input type="checkbox"/>	<input type="checkbox"/>	(k) Snores, blocked nose or poor sleep	<input type="checkbox"/>	<input type="checkbox"/>
(e) Says 'eh what?' or 'pardon' a lot	<input type="checkbox"/>	<input type="checkbox"/>	(l) Speech seems behind other children's	<input type="checkbox"/>	<input type="checkbox"/>
(f) Needs the television turned up	<input type="checkbox"/>	<input type="checkbox"/>	(m) Any suspected ear problem	<input type="checkbox"/>	<input type="checkbox"/>
(g) May be irritable or withdrawn	<input type="checkbox"/>	<input type="checkbox"/>			

Q3. Please answer the following questions from your OBSERVATION REGISTER:-

a) Was this child recruited from: computer records **OR** referral

b) If he/she was recruited from their records please state:

How many episodes of OME have they had in the last 12 months

How many episodes of OM have they had in the last 12 months

Have they had 1 or more entries in their notes over the last 12 months for

- i) hearing loss **Yes / No** if yes, how many
- ii) snoring **Yes / No** if yes, how many
- iii) behaviour concerns **Yes / No** if yes, how many
- iv) speech concerns **Yes / No** if yes, how many
- v) educational concerns **Yes / No** if yes, how many

Q4. INCLUSION AND EXCLUSION CRITERIA (go through with parent/guardian)

- a) Is your child too young to be at school or older than 11 years? Yes No
- b) Does your child have grommets in place? Yes No
- c) Is your child already listed for an operation to have grommets put in? Yes No
- d) Has your child had a recent nose bleed (within the last 3 weeks) or more than one episode of nose bleeding over the past 6 months? Yes No
- e) Does your child have an allergy to latex? Yes No
- f) Has a clinician made you aware that your child may need early referral for glue ear? (e.g. children with Down's, cleft palate, Kartagener's, Primary Ciliary Dyskinesia, immunodeficiency states etc.) Yes No
- g) Does the nurse believe your child will be **unable** to comply with the technique of autoinflation? Yes No

If the answer to **ALL** these questions is **NO** the child is **ELIGIBLE** for screening please go to Question 5

If at least one answer is **YES** the child is **NOT ELIGIBLE** for screening, please give the parent an explanation as to why – refer to your study manual. Please go to Question 6

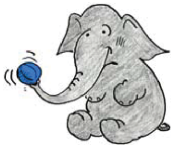
Q5. CONSENT (parent informed about trial)

- Consent obtained
- Consent form taken away, to be posted back

If parent refuses to consent, ask them if they are happy to give their reasons, if they are please state them here.....

- Child (parent) given a copy of their signed consent form and patient information sheet(s)

Q6. Nurse's signature: _____ **Date:** _____



Study ID Number:

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Date of Appointment:

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

Q1. OTOSCOPY FINDINGS *please circle:*

	mostly clear	RIGHT	LEFT
<i>If you suspect wax or perforation to be a problem check by using tympanometry</i>	mostly wax	RIGHT	LEFT
	perforation	RIGHT	LEFT
	grommet	RIGHT	LEFT

exclude child from study ←

Q2. TYMPANOMETRY

Please circle one option for each ear and fill in the pressure reading

RIGHT EAR				LEFT EAR			
A	C1	B	C2	A	C1	B	C2
Pressure =daPa				Pressure =daPa			

**Please attach
print out here**

Large amounts of wax (>95% obscured) and a low compliance (<0.2ml)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	if yes, exclude
Perforation, flat line and high volume (>1.5ml)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	if yes, exclude

Q3. ELIGIBILITY

- a) If **NOT ELIGIBLE**, please tick box indicating that the child has been excluded from study and explanation has been given to the parent/guardian and child as to why. If child is **NOT ELIGIBLE** please go to Question 5
- b) If **ELIGIBLE**, continue to Question 4

Q4. PARENT INFORMED ABOUT NEXT PART OF STUDY_

Yes No

If parent does not wish to continue please give their reason(s) for refusal

.....

.....

Q5. 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. 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.

Q6. Nurse's signature: _____

Date: _____

AIRS: Baseline – About You and Your Child



Study ID Number:

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Date of Appointment:

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

1. Does your child have any of these?

- Asthma Yes No
- Hay fever Yes No
- Eczema Yes No

TO BE COMPLETED BY THE PARENT

Nurse – put green copy back in folder once completed

2. Has your child had antibiotics for an ear infection or ear problem in the last month?

- Yes No

3. What is the highest grade of school you have completed?

	<u>You</u>	<u>Partner</u>
School to 16, no qualifications	<input type="checkbox"/>	<input type="checkbox"/>
School to 16, GCSE's/O'Levels	<input type="checkbox"/>	<input type="checkbox"/>
Sixth form school or college, A' levels, ND	<input type="checkbox"/>	<input type="checkbox"/>
Highers, Scotvec or NVQ	<input type="checkbox"/>	<input type="checkbox"/>
University degree	<input type="checkbox"/>	<input type="checkbox"/>
Professional or postgraduate degree	<input type="checkbox"/>	<input type="checkbox"/>

4. Which of the following best describes your current marital status?

- Married or living with partner Single Separated or divorced Widowed

5. Which of the following best describes YOUR CHILD'S racial background

- White Oriental Afro-Caribbean Bangladeshi / Indian Mixed race Other group

If mixed race or other group, please specify

6. Is English the first language spoken at home?

- Yes No

If NO, which language is used?

7. What is your annual gross family income (before any tax deductions and including Benefits)?

- less than £10k £10k - £20k £21k - £30k £31k - £40k £41k - £50k over £50k



Study ID Number:

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Date of Appointment:

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

4 week diary collected	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Reward Chart collected	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

IF THE CHILD WAS RANDOMISED TO STANDARD CARE PLEASE START WITH QUESTION 2

Q1. AUTOINFLATION ADHERENCE AND USE

a) Did your child perform the autoinflation?

not at all
 some of the time
 most of the time
 all of the time

b) How many times per day did your child use it?

0
 1
 2
 3
 More than 3

c) How many blows in each nostril did your child do?

0
 1
 More than 1

d) How easy do you think your child found the autoinflation to do?

Extremely easy	Very easy	Moderately easy	Fairly easy	Not very easy	Not easy at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

e) Could you describe any discomfort your child experienced whilst doing the autoinflation

.....

.....

Was it at the start of the study? Yes No

Was it throughout the study? Yes No

Q2. CHECK REFERRAL STATUS

Has your child been referred to an ENT surgeon Yes No

If yes, has the surgeon recommended surgery Yes No

If yes, do you have an appointment yet Yes No
 date

Q3.CHECK ADVERSE EVENTS / SIDE EFFECTS

Increase in respiratory infections Yes No

Occurrence of nose bleeds Yes No

If child and/or parents are concerned about their side effects or it is severe they should be referred to the GP

If any Adverse Events are reported please complete an Adverse Event Form with parent present

AIRS: 1 Month Measures Form



Study ID Number:

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PAGE 2 of 2

Q4. OTOSCOPY please circle for each ear:

	mostly clear	RIGHT	LEFT
}	mostly wax	RIGHT	LEFT
	perforation	RIGHT	LEFT
	grommet	RIGHT	LEFT

child continues with study ←

If you suspect wax or perforation to be a problem check by using tympanometry

Q5. TYMPANOMETRY

a) Please circle one option for each ear and fill in the pressure reading

RIGHT EAR				LEFT EAR			
A	C1	B	C2	A	C1	B	C2
Pressure =daPa				Pressure =daPa			

Please attach print out here

- b) Large amounts of wax (>95% obscured) and a **low** compliance (<0.2ml) Yes No
- c) Perforation, **flat line** and **high volume** (>1.5ml) Yes No

Q6. COMMENT: cooperative non-cooperative

Q7. AUTOINFLATION GROUP - IF CHILD HAD AT LEAST ONE B TYMPANOGRAM AT THIS VISIT

Has the child been given more Otovent supplies? Yes No

If No, why not?

Q8. STANDARD CARE GROUP ONLY

Has your child used any autoinflation devices between baseline and 1 month?

Yes No

Q9. 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.

Q10. Nurse's signature: _____ **Date:** _____



Study ID Number:

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Date of Appointment:

d	d	m	m	y	y	y	y
---	---	---	---	---	---	---	---

8 week diary collected	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Reward Chart collected	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

Q1. Please tick one of the following:

- Child randomised to Autoinflation and had **at least one B tympanogram at 1 Month** (go to Q2)
- Child randomised to Autoinflation and had **no B tympanograms at 1 Month** (go to Q3)
- Child randomised to Standard Care (go to Q3)

Q2. AUTOINFLATION ADHERENCE

a) Did your child perform the autoinflation

- not at all
 some of the time
 most of the time
 all of the time

b) How many times per day did your child use it?

- 0
 1
 2
 3
 More than 3

c) How many blows in each nostril did your child do?

- 0
 1
 More than 1

d) Could you describe any discomfort your child experienced whilst doing the autoinflation

.....

.....

Q3. CHECK REFERRAL STATUS

Has your child been referred to an ENT surgeon Yes No

If yes, has the surgeon recommended surgery Yes No

If yes, do you have an appointment yet Yes No

When

Q4. CHECK ADVERSE EVENTS/SIDE EFFECTS

Increase in respiratory infections Yes No

Occurrence of nose bleeds Yes No

If child and/or parents are concerned about their side effects or it is severe they should be referred to the GP

If any Adverse Events are reported please complete an Adverse Event Form with parent present



Study ID Number:

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Q5. OTOSCOPY please circle one for each ear:

- | | | | |
|---|---|-------|------|
| | mostly clear | RIGHT | LEFT |
| } | mostly wax | RIGHT | LEFT |
| | perforation | RIGHT | LEFT |
| | child continues with study ← grommet | RIGHT | LEFT |

If you suspect wax or perforation to be a problem check by using tympanometry

Q6. TYMPANOMETRY

a) Please circle one option for each ear and fill in the pressure reading

RIGHT EAR				LEFT EAR			
A	C1	B	C2	A	C1	B	C2
Pressure =daPA				Pressure =daPA			

**Please attach
print out here**

- b) Large amounts of wax (>95% obscured) and a **low** compliance (<0.2ml) Yes No
- c) Perforation, **flat line** and **high volume** (>1.5ml) Yes No

Q7. COMMENT: cooperative non-cooperative

Q8. Has your child used any autoinflation devices between 1 and 3 months (for autoinflation group this refers to devices other than the Otovent given to you for study purposes)?

Yes No

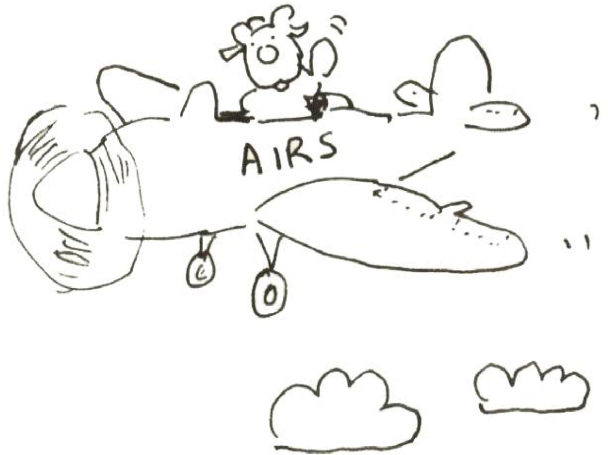
Q9. OPTIONAL

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.

Q10. Nurse's signature: _____ **Date:** _____

AIRS



Diary 1

For YOU

This is your diary and you and your grown ups need to fill it in at the end of each week – they will ask you to remember how you have felt over the week and then they will write it down so think hard because we can't wait to hear how you've been feeling.

For the GROWN-UPS of the AUTO-INFLATION GROUP

Please remember that your child needs to blow the balloon up (once in each nostril, three times throughout the day) at whatever time suits you best but please do it at the same time each day

WEEK 1 (EXAMPLE)

1. How many days has your child had earache (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
	✓						

2. How many days has your child had any hearing loss (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
		✓					

3. How many days has your child had a problem concentrating (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
		✓					

4. How many days has your child had off school / playgroup (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
			✓				

5. How many days has your child received pain relief (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
				✓			

6. How many **nights** has your child had disturbed sleep (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
			✓				

Thinking only of this week:- tick whether or not your child had the symptoms in the table below and for the ones they did have use the following ratings to rate how bad each one got at its worst in the week

0 = not present at all 1 = very little problem 2 = slight problem 3 = moderately bad 4 = bad 5 = very bad 6 = as bad as it could be

Has you child.....

- been clumsy / off balance
- been unwell / had a temperature
- had a runny nose
- had a blocked nose / been snoring
- had any nosebleeds

Yes	No	how bad at its worst
✓		4
	✓	
✓		3
	✓	
	✓	

WEEK 1

1. How many days has your child had earache (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. How many days has your child had any hearing loss (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. How many days has your child had a problem concentrating (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. How many days has your child had off school / playgroup (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. How many days has your child received pain relief (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. How many **nights** has your child had disturbed sleep (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Thinking only of this week:- tick whether or not your child had the symptoms in the table below and for the ones they did have use the following ratings to rate how bad each one got at its worst in the week

0 = not present at all 1 = very little problem 2 = slight problem 3 = moderately bad 4 = bad 5 = very bad 6 = as bad as it could be

Has your child.....

been clumsy / off balance

been unwell / had a temperature

had a runny nose

had a blocked nose / been snoring

had any nosebleeds

Yes	No	how bad at its worst
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

WEEK 2

1. How many days has your child had earache (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. How many days has your child had any hearing loss (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. How many days has your child had a problem concentrating (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. How many days has your child had off school / playgroup (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. How many days has your child received pain relief (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. How many **nights** has your child had disturbed sleep (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Thinking only of this week:- tick whether or not your child had the symptoms in the table below and for the ones they did have use the following ratings to rate how bad each one got at its worst in the week

0 = not present at all 1 = very little problem 2 = slight problem 3 = moderately bad 4 = bad 5 = very bad 6 = as bad as it could be

Has you child.....

been clumsy / off balance

been unwell / had a temperature

had a runny nose

had a blocked nose / been snoring

had any nosebleeds

Yes	No	how bad at its worst
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

WEEK 3

1. How many days has your child had earache (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. How many days has your child had any hearing loss (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. How many days has your child had a problem concentrating (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. How many days has your child had off school / playgroup (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. How many days has your child received pain relief (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. How many **nights** has your child had disturbed sleep (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Thinking only of this week:- tick whether or not your child had the symptoms in the table below and for the ones they did have use the following ratings to rate how bad each one got at its worst in the week

0 = not present at all 1 = very little problem 2 = slight problem 3 = moderately bad 4 = bad 5 = very bad 6 = as bad as it could be

Has your child.....

been clumsy / off balance

been unwell / had a temperature

had a runny nose

had a blocked nose / been snoring

had any nosebleeds

Yes	No	how bad at its worst
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	

WEEK 4

1. How many days has your child had earache (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. How many days has your child had any hearing loss (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. How many days has your child had a problem concentrating (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. How many days has your child had off school / playgroup (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. How many days has your child received pain relief (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. How many **nights** has your child had disturbed sleep (please put a cross in the relevant box)

0	1	2	3	4	5	6	7
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Thinking only of this week:- tick whether or not your child had the symptoms in the table below and for the ones they did have use the following ratings to rate how bad each one got at its worst in the week

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Has you child.....

been clumsy / off balance

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had a runny nose

had a blocked nose / been snoring

had any nosebleeds

Yes	No	how bad at its worst
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	



You are a star - well done you
finished your first diary.

AIRS: Costs to parents 1

To be completed when taking BASELINE measures

Study ID number:

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1. SELF MEDICATION USE FOR EAR PROBLEMS

Over the **last 3 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. TIME OFF WORK

- a) Have you had to take any time off paid work in the **last 3 months** because of your child's ear problems?
Yes No
If yes, how many days have you needed to take off work in the **last 3 months** _____ days
- b) Has your partner, or any other members of your family needed to take time off work because of your child's ear problems?
Yes No
If yes, how many days have you needed to take off work in the **last 3 months** _____ days

3. OTHER OUT OF POCKET EXPENSES

During the **last 3 months** have you had any extra expenses because of your child's ear problems?
Please only include costs that arose because of your child's ear problem.

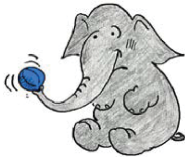
Examples might include: additional child care costs or taxi fares and other travel expenses.

Yes No

If yes, please say what this/these expense(s) were:-

Type of expense, please state	Approximate value in £s
<i><u>EXAMPLE:</u> taxi fare to collect from school early</i>	£15
Expense 1.....	
Expense 2.....	
Expense 3.....	
Expense 4.....	

*To be done 6 MONTHS AFTER BASELINE
by computer search*



Study ID Number:

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Date Performed:

d	d	m	m	y	y	y	y
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All questions refer to the previous 6 month

Q1. ALL APPOINTMENTS

(excluding AIRS assessment appointments)

	Ear related	Non-ear related
List the dates of surgery appointments with GP		
List the dates of surgery appointments with practice nurse		
List the dates of surgery appointments with health visitor		
List the dates of home visits by GP		
List the dates of home visits by district nurse		
List the dates of home visits by health visitor		
List the dates of telephone consultations with GP		
List the dates of telephone consultations with practice nurse		
List the dates of out of hours consultations with GP		

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Q2. 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

b) Decongestants and antihistamines:

date name dose days

date name dose days

date name dose days

c) Analgesics:

date name dose days

date name dose days

Q3. PRESCRIBED MEDICATION FOR OTHER REASONS

date name dose days

date name dose days

date name dose days

date name dose days

Q4. ANY INVESTIGATIONS IN THEIR RECORDS

e.g. blood tests / x-rays,

please state, what Date: Number

please state, what Date: Number

please state, what Date: Number

Q5. OUTPATIENT HOSPITAL REFERRALS

Date

main reason

to where?

ENT audiology other

please state

Date

main reason

to where?

ENT audiology other

please state

Please turn over

--	--	--	--	--	--	--	--

Date
 main reason
 to where?

ENT audiology other
 please state

Date
 main reason
 to where?

ENT audiology other
 please state

Q6. REFERRAL FOR SPEECH THERAPY

Date
 main reason
 to where?

Date
 main reason
 to where?

Q7. REFERRAL TO COMMUNITY HEALTHCARE PROFESSIONAL (e.g. community paediatrician)

Date
 main reason
 to where?

Date
 main reason
 to where?

Date
 main reason
 to where?

Date
 main reason
 to where?

Q8. HOSPITALISATION

Was the child admitted to hospital for:

- a) grommets / t-tubes / ventilation tubes: Yes / No
- b) adenoidectomy: planned Yes / No
- done Yes / No
- c) other reason Yes / No

if yes, please state

If Yes to a) or b) or c) please state:-

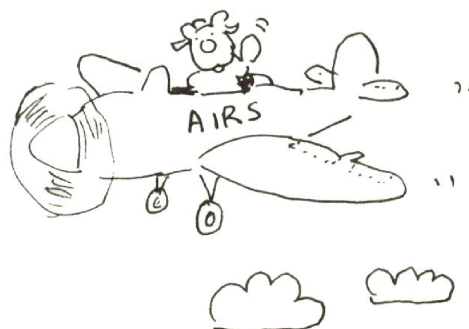
Name of hospital	Name of ward	Date of admission	Date of discharge
.....
.....

Q9. Nurse's signature: _____ **Date:** _____

HUI23P4E.15Q

Health Utilities Index Mark 2 and Mark 3 (HUI2/3)
15-item questionnaire for self administered, proxy-assessed
"Four week" Health Status Assessment

AIRS



1 Month

Study ID Number:

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Date questionnaire completed:

d	d	m	m	y	y	y	y
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Permission for the use of this document was obtained from:

Health Utilities Inc. (HUInc)

88 Sydenham Street

Dundas ON, Canada L9H 2V3

Tel [REDACTED]

Fax [REDACTED]

<http://www.healthutilities.com>

Instructions for parents / guardians

This questionnaire contains a set of questions which ask about various aspects of your child's health. When answering these questions please think about your child's health and ability to do things on a day-to-day basis, **during the past 4 weeks**. To define the past 4 week period, please think about what the date was 4 weeks ago and recall the major events that your child has experienced during this period. Please focus your answers on your child's abilities, disabilities, and how they have felt during the past 4 weeks.

You may feel that some of these questions do not apply to your child, but it is important that we ask the same questions to everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently.

Please read each question and consider your answers carefully. For each question, please select **one** answer that **best describes** your child's level of ability or disability during the past 4 weeks. Please indicate the selected answer by **circling** the letter (a, b, c,) beside the answer.

All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your child's abilities and feelings.

1. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to see well enough to read ordinary newsprint?
 - a. Able to see well enough without glasses or contact lenses
 - b. Able to see well enough with glasses or contact lenses
 - c. Unable to see well enough even with glasses or contact lenses
 - d. Unable to see at all

2. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to see well enough to recognise a friend on the other side of the street?
 - a. Able to see well enough without glasses or contact lenses
 - b. Able to see well enough with glasses or contact lenses
 - c. Unable to see well enough even with glasses or contact lenses
 - d. Unable to see at all

3. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to hear what was said **in a group conversation with at least three other people**?
 - a. Able to hear what is said without a hearing aid
 - b. Able to hear what is said with a hearing aid
 - c. Unable to hear what is said even with a hearing aid
 - d. Unable to hear what is said, but does not wear a hearing aid
 - e. Unable to hear at all

4. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to hear what was said **in a conversation with one other person in a quiet room?**
- a. Able to hear what is said without a hearing aid
 - b. Able to hear what is said with a hearing aid
 - c. Unable to hear what is said even with a hearing aid
 - d. Unable to hear what is said, but does not wear a hearing aid
 - e. Unable to hear at all
5. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to be understood when speaking his/her own language with people who do not know them?
- a. Able to be understood completely
 - b. Able to be understood partially
 - c. Unable to be understood
 - d. Unable to speak at all
6. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to be understood when speaking with people who know them well?
- a. Able to be understood completely
 - b. Able to be understood partially
 - c. Unable to be understood
 - d. Unable to speak at all

Please turn over

7. Which **ONE** of the following best describes your child's feelings during the past 4 weeks?
- a. Happy and interested in life
 - b. Somewhat happy
 - c. Somewhat unhappy
 - d. Very unhappy
 - e. So unhappy that life is not worthwhile
8. Which **ONE** of the following best describes the pain and discomfort your child has experienced during the past 4 weeks?
- a. Free of pain and discomfort
 - b. Mild to moderate pain or discomfort that prevents no activities
 - c. Moderate pain or discomfort that prevents a few activities
 - d. Moderate to severe pain or discomfort that prevents some activities
 - e. Severe pain or discomfort that prevents most activities

9. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to walk?

Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches or a walker.

- a. Able to walk around the neighbourhood without difficulty, and without walking equipment
- b. Able to walk around the neighbourhood with difficulty, but does not require walking equipment or the help of another person
- c. Able to walk around the neighbourhood with walking equipment, but without the help of another person.
- d. Able to walk only short distances with walking equipment, and requires a wheelchair to get around the neighbourhood
- e. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood.
- f. Unable to walk at all

Please turn over

10. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to use his/her hands and fingers?

Note: Special tools refers to hooks for buttoning clothes, gripping devices for opening jars or lifting small items, and other devices to compensate for limitations of hands and fingers.

- a. Full use of two hands and ten fingers
- b. Limitations in the use of hands or fingers, but does not require special tools or the help of another person
- c. Limitations in the use of hands or fingers, independent with use of special tools (does not require the help of another person)
- d. Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with use of special tools)
- e. Limitations in the use of hands or fingers, requires the help of another person for most tasks (not independent even with use of special tools)
- f. Limitations in the use of hands or fingers, requires the help of another person for all tasks (not independent even with use of special tools)

11. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to remember things?
- a. Able to remember most things
 - b. Somewhat forgetful
 - c. Very forgetful
 - d. Unable to remember anything at all
12. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to think and solve day to day problems?
- a. Able to think clearly and solve day to day problems
 - b. Has a little difficulty when trying to think and solve day to day problems
 - c. Has some difficulty when trying to think and solve day to day problems
 - d. Has great difficulty when trying to think and solve day to day problems
 - e. Unable to think or solve day to day problems

Please turn over

13. Which **ONE** of the following best describes your child's ability, during the past 4 weeks, to perform basic activities?
- a. Eats, bathes, dresses and uses the toilet normally
 - b. Eats, bathes, dresses and uses the toilet independently with difficulty
 - c. Requires mechanical equipment to eat, bathe, dress or use the toilet independently
 - d. Requires the help of another person to eat, bathe, dress or use the toilet
14. Which **ONE** of the following best describes your child's feelings during the past 4 weeks?
- a. Generally happy and free from worry
 - b. Occasionally fretful, angry, irritable, anxious or depressed
 - c. Often fretful, angry, irritable, anxious or depressed
 - d. Almost always fretful, angry, irritable, anxious or depressed
 - e. Extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help

15. Which **ONE** of the following best describes the pain or discomfort your child has experienced during the past 4 weeks?
- a. Free of pain and discomfort
 - b. Occasional pain or discomfort. Discomfort relieved by non-prescription medication or self-control activity without disruption of normal activities
 - c. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional; disruption of normal activities
 - d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort requires prescription medication for relief
 - e. Severe pain or discomfort. Pain not relieved by medication and constantly disrupts normal activities
16. Overall how would you rate your child's health during the past 4 weeks?
- a. Excellent
 - b. Very good
 - c. Good
 - d. Fair
 - e. Poor

Please turn over

17. Who provided information used to answer the questions in this questionnaire? (please indicate all that apply)
- a. Person recording the answers on the form
 - b. Child
 - c. Others. Please list the relationship between your child and each person who provided information:
 - 1.
 - 2.
 - 3.
 - 4.

18. Who recorded the answers on this questionnaire form?
- a. Parent of the child
 - b. Other (please specify)

**Many thanks for all your
help**

BASELINE MEASURES

Date of completion

d	d	m	m	y	y	y	y
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Study ID Number

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OMQ-14: Quality of Life in children's ear problems

Questionnaire on impact of ear problems in children 3-9 years*

How parent/caregiver should complete this questionnaire

Some children are more affected than others, and in differing ways. Help can best be given, and improvement best assessed, when this impact is measured in a standard way that bridges these differences. The following 14 questions cover some of the most important ways in which ear problems affect children's quality of life. For some questions an interpretation may be involved, not just an observation, so an "unsure" response is permitted. But please try to avoid this, by choosing the response that best describes just how affected your child has been over the last 3 months, and placing a tick-mark (✓). On finishing, please check that you have answered all questions. The answers will be kept confidential to the clinic or research team.

All questions refer to the period of the last 3 months.

		FOR OFFICE USE ONLY
1. Over the last three months, taking everything into account, how has your child's health has been ?		
Very good	<input type="checkbox"/>	
Good	<input type="checkbox"/>	
Only fair, or poor	<input type="checkbox"/>	
2. How many times has he/she had trouble with his/her ears ?		
Not at all	<input type="checkbox"/>	
Once	<input type="checkbox"/>	
2-3 times	<input type="checkbox"/>	
4 or more times	<input type="checkbox"/>	
3. How many ear infections has he/she had ? <i>(i.e. severe pain in his/her ear, possibly with a temperature, smelly discharge in ear canal, or hole in eardrum)</i>		
0	<input type="checkbox"/>	
1	<input type="checkbox"/>	
2-3	<input type="checkbox"/>	
4 or more	<input type="checkbox"/>	

*. Exceptionally, the questionnaire can be used after a child becomes 9 years old (see User Manual)

All questions refer to the last 3 months.

4. How many times has he/she had an earache ?	
0	<input type="checkbox"/>
1	<input type="checkbox"/>
2-3	<input type="checkbox"/>
4 or more	<input type="checkbox"/>

FOR OFFICE USE ONLY

5. How would you describe your child's hearing ?	
Normal	<input type="checkbox"/>
Slightly below normal	<input type="checkbox"/>
Poor	<input type="checkbox"/>
Very poor	<input type="checkbox"/>
Not sure	<input type="checkbox"/>

6. Has he/she mis-heard words when not looking at you ?	
No	<input type="checkbox"/>
Rarely	<input type="checkbox"/>
Often	<input type="checkbox"/>
Always	<input type="checkbox"/>
Not sure	<input type="checkbox"/>

7. Has he/she had difficulty hearing when with a <u>group</u> of people ? (ie not one-to-one)	
No	<input type="checkbox"/>
Rarely	<input type="checkbox"/>
Often	<input type="checkbox"/>
Always	<input type="checkbox"/>
Not sure	<input type="checkbox"/>

All questions refer to the last 3 months.

FOR OFFICE USE ONLY

8. How long can he/she concentrate on a game or a task <u>you have given him/her to do</u> ?	
Up to 2 minutes	<input type="checkbox"/>
Up to 5 minutes	<input type="checkbox"/>
5-10 minutes	<input type="checkbox"/>
10-15 minutes	<input type="checkbox"/>
More than 15 minutes	<input type="checkbox"/>

9. How often does he/she seek your attention unnecessarily ? <i>(e.g. in an unusually dependent way, asking for help for a task he/she can do alone, demanding to be carried, demanding you play with them, following you around)</i>	
Less than once a month	<input type="checkbox"/>
Once a month	<input type="checkbox"/>
Once a week	<input type="checkbox"/>
Once a day	<input type="checkbox"/>
Two or more times per day	<input type="checkbox"/>

10. How often is he/she unhappy for no apparent reason ?	
Less than once a month	<input type="checkbox"/>
Once a month	<input type="checkbox"/>
Once a week	<input type="checkbox"/>
Once or more per day	<input type="checkbox"/>

11. Has he/she mispronounced the beginnings or ends of words ?	
No	<input type="checkbox"/>
Rarely	<input type="checkbox"/>
Often	<input type="checkbox"/>
Always	<input type="checkbox"/>

12. Has his/her speech been behind (less developed than) that of children of similar age ?	
No	<input type="checkbox"/>
A little	<input type="checkbox"/>
Moderately or a lot	<input type="checkbox"/>
Not sure	<input type="checkbox"/>

FOR OFFICE
USE ONLY

13. Have you often felt tired ?	
Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

14. Has your child needed more attention than other children ?	
Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

Responding person providing information

A. Would you describe your educational qualifications as:

Left school before age 15 years	<input type="checkbox"/>	Usual school exams for 15-16	<input type="checkbox"/>
Usual school exams for 17-18	<input type="checkbox"/>	Further qualifications, but not university degree	<input type="checkbox"/>
University degree	<input type="checkbox"/>	Not applicable	<input type="checkbox"/>

Score 1
Score 2

B. Are you:

Child's mother	<input type="checkbox"/>	Child's father	<input type="checkbox"/>
<input type="checkbox"/> Other (please specify).....			
Your own age.....		Age of child:.....	

Score 3

C. If any impacts from the ear problems of your child which you think important have not been covered above, please mention up to 4 here:

1.
2.
3.
4.