

Practice Headed Paper

DRAFT LETTER FOR INVITATION TO SCREENING (Parent letter 1)

To the parents/guardians of.....

Our practice is taking part in a research project looking at "glue-ear" in children – its medical name is "Otitis Media with Effusion". The research is funded by the NIHR Health Technology Assessment Programme and managed by the University of Southampton. We have enclosed an information sheet about the study and also one for your child.

"Glue-ear" is a very common condition in the early school years, and it affects about 4 out of 5 children before their 10th birthday. It is also particularly common over the winter months. It is a type of catarrh, sticky mucus or "glue" behind the eardrum, which can cause the child to lose some hearing and lead to a variety of different problems. Most children affected by this condition will recover on their own over 3 months, however a small percentage may need further medical treatment.

Your child has been invited because they are 4-6 years old and we have shown in other studies that even seemingly healthy children in this age range quite commonly get glue ear in the winter and spring terms (about 1 in 4 children on average and sometimes higher).

Please use this checklist of any ear concerns for the last 3 months and if your child has a tick against one or more of these then glue ear is a possibility and at very least worth excluding, so we would like to invite your child into the practice to have their ears screened (and if found positive - treated).

SYMPTOM CHECKLIST

A prolonged or bad cold, cough or chesty infection	<input type="checkbox"/> Yes	<input type="checkbox"/> No
An earache	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Appears to mishear what is said	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Hearing loss has been suspected by anyone	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Says 'eh what?' or 'pardon' a lot	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Needs the television turned up	<input type="checkbox"/> Yes	<input type="checkbox"/> No
May be irritable or withdrawn	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Appears to be lip reading	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Not doing so well at school as you or the teacher think <i>e.g.</i> with reading	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Has noises in the ear or is dizzy	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Snores, blocked nose or poor sleep	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Speech seems behind other children's	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Any suspected ear problem	<input type="checkbox"/> Yes	<input type="checkbox"/> No

If your child has not had any of these symptoms or concerns in the last 3 months then there is no benefit of coming in for a screening just now and there is no need to read any further, but we would ask that you kindly return the completed reply slip below.

If your child has however had one or more of these symptoms or concerns then it is good to confirm if they actually have glue ear as the cause using a simple quick painless test, (using a soft ear probe like a headphone). The study will then compare a treatment technique called autoinflation and your doctor's usual management against your doctor's usual management only. Autoinflation involves your child blowing up a special balloon using their nose rather than their mouth (see picture). Your child will have a 50:50 chance of receiving autoinflation straight away to take for one to three months, with all study children receiving usual clinical care for their glue ear.



If a study child in the group not receiving autoinflation still has glue ear after a test three months later (the more persistent or troublesome cases) then they will be offered autoinflation to use if they want. If your child does take part in the study we would just ask you to keep a simple diary of their symptoms with their help. Following the initial appointment the practice research nurse will make two appointments to see you and your child over three months to monitor their ears. She will ask you to complete a questionnaire on these visits.

You are under no obligation to take part in the study. If you decide not to take part in this study it will not affect the care that you or your children would receive from the practice in any way. You have the right to withdraw from the study at any time and if you do so it will not affect the care that you or your child(ren) receive from the practice.

If you have any questions or concerns please do not hesitate to contact the research nurse at the practice on the telephone number above.

If you are interested in attending an initial appointment, with your child, for a fuller explanation and discussion of the study and a confirmation (diagnostic) screening by the research nurse, please complete the attached reply slip and return it in the stamped addressed envelope. It would be helpful if you would kindly return this reply slip even if you do not wish to attend an appointment.

Please read the enclosed Patient Information Sheet and please give your child the one we've enclosed especially for them.

Yours sincerely

Dr Doctor

Study ID number:

**PLEASE TICK YES TO EITHER A or B
then return to the practice in stamped addressed envelope provided**

A **My child has one or more symptoms in the checklist** YES

I agree / I do not agree for my child and I to be seen by the nurse for a fuller explanation of the study and to confirm if they have glue ear using an accurate diagnostic test

(the tympanometry screening for glue ear, will only be done if you agree on the day)

Your Name:

Child's Name:

Tel:

OR

B **My child does not have any of the symptoms in the checklist
and therefore does not need a screening test** YES

Practice Headed Paper

DRAFT LETTER FOR INVITATION TO SCREENING (Parent letter 2)

To the parents/guardians of.....

Our practice is taking part in a research project looking at "glue-ear" in children – its medical name is "Otitis Media with Effusion". The research is funded by the NIHR Health Technology Assessment Programme and managed by the University of Southampton. We have enclosed an information sheet about the study and also one for your child.

"Glue-ear" is a very common condition affecting about 4 out of 5 children before their 10th birthday, and is particularly common over the winter months. It is a type of catarrh, or "glue" behind the eardrum, which can cause the child to lose some hearing and lead to a variety of different problems. Most children affected by this condition will recover on their own, however a small percentage may need further medical referral and treatment.

If your child has glue ear in one or both ears they could join in with our research. The study will compare a treatment technique called autoinflation and your doctor's usual management against your doctor's usual management only. Autoinflation involves your child blowing up a special balloon using their nose rather than their mouth (see picture).



Your child will have a 50:50 chance of receiving autoinflation straight away to take for one to three months, with all study children receiving usual clinical care for their glue ear.

If any study child in the group not receiving autoinflation still has glue ear after a test three months later (the more persistent or troublesome cases) then they will be offered autoinflation to use if they want. If your child does take part in the study we would ask you to just keep a simple diary of their symptoms with their help. Following the initial appointment the practice research nurse will make two appointments to see you and your child over three months to monitor their ears. She will ask you to complete a questionnaire on these visits.

Your child has been invited because your practice has noted from their records that they have had one or more ear infections or ear related problems over the last year and he/she may therefore have developed glue ear.

You are under no obligation to take part in the study. If you decide not to take part in this study it will not affect the care that you or your child(ren) receive from the practice in any way. You have the right to withdraw from the study at any time and if you do so it will not affect the care that you or your child(ren) receive from the practice.

If you have any questions or concerns please do not hesitate to contact the research nurse at the practice on the telephone number above.

If you are interested in attending an appointment, with your child, for a fuller explanation and discussion of the study and an initial confirmation (diagnostic) screening by the research nurse, please complete the attached reply slip and kindly return it in the stamped addressed envelope. It would be helpful if you would return this reply slip even if you do not wish to attend an appointment.

Please read the enclosed Patient Information Sheet and please give your child the one we've enclosed especially for them.

Yours sincerely

Dr Doctor

Study ID number:

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Please circle and return to the practice in stamped addressed envelope provided.

I agree / I do not agree for my child and I to be seen by the nurse for a fuller explanation of the study and to have an initial screening for glue ear, if I agree on the day

Your Name:

Child's Name:

Tel: