

rAOM Talking Points (Screening Phase)

- Your child has had one or more ear infections. Children’s Hospital of Pittsburgh of UPMC has a research program for children with multiple episodes of ear infections.
- Sometimes doctors treat children with recurrent ear infections with surgery, which involves placing ventilating tubes in the ear drum. Other times, doctors choose to continue to treat recurrent ear infections with oral antibiotics. We truly do not know which option is better.
- We are trying to identify a group of children with recurrent ear infections, defined as 3 ear infections in 6 months or 4 in the past 12 months with at least 1 episode in the past 6 months.
- We would like to follow your child over time and have our study team examine his/her ears and confirm at least 2 ear infections ourselves.
- Children with recurrent ear infections, of which our study team has diagnosed 1, will be asked to participate in Part 2 of the study where we will try to determine which children are most likely to benefit from ear tubes. We are not asking you to make a decision about Part 2 today. We are simply asking to follow your child for further ear infections.
- Recurrent ear infections are a common problem in children. That is why the National Institutes of Health (NIH) has supported our study, to find out which is the best approach.
- If you decide to enroll your child in our study, we would like to see her/him and document the appearance of the ear drum if your child has had cold symptoms that persist for 5 days or longer or within 48 hours of any symptom suggestive of an ear infection.
- We will contact you every 2 weeks to monitor any new cold symptoms your child may have.
- If your child has an ear infection, s/he will be prescribed antibiotics, as we would routinely treat an ear infection. The treatment is not part of the study, and we are not testing any new drugs or procedures.
- We will continue to follow your child until he or she meets criteria for recurrent ear infections or for 12 months if your child does not develop episodes of ear infections.
- We will be available 24/7 to answer any questions you may have, and arrange for your child to be seen when you have any concerns.
- We will provide compensation for all study visits. (\$15)

rAOM Talking Points (Randomization Phase)

- Your child has another ear infection. Children’s Hospital of Pittsburgh of UPMC has a research program for children with recurrent (multiple) episodes of ear infections.
- Sometimes doctors treat children with recurrent ear infections (3 or more episodes in 6 months or 4 or more episodes in 12 months) with surgery, which involves placing ventilating tubes in the ear drum. Other times, doctors choose to continue to treat recurrent ear infections with oral antibiotics. We truly do not know which option is better. So, let us talk about pros and cons of each option.
- Let’s start with oral antibiotics:
 - We know that treatment with oral antibiotics helps resolve symptoms of an ear infection.

- We know that oral antibiotics can have side effects, the most frequent of which are diarrhea and diaper rash.
- We also know that overuse of oral antibiotics can make bacteria become resistant, and then some antibiotics do not work.
- What about tubes:
 - There might be a reduction of 1-2 ear infections per year.
 - In children with tubes, we can treat ear infections with antibiotic ear drops instead of oral antibiotics. This could decrease the side effects of antibiotics and may decrease the likelihood of bacteria becoming resistant.
 - Performing surgery to place ear tubes, however, may come with the following risks: (1) risks of anesthesia (which is generally not recommended before age 3 years), (2) possible drainage through the tubes after surgery, (3) blockage of the tube or its premature falling out of place, and (4) scars on the ear drum or persistent perforation of the ear drum.
- That is why the National Institutes of Health (NIH) has supported our study, to find out whether it is better to treat children with recurrent episodes of ear infections with ear tubes or oral antibiotics when they have an ear infection, and eventually tubes if they keep on having recurrent ears infections.
- There is a 50/50 chance that s/he will have ear tubes placed within 2 weeks, or will be treated with oral antibiotics when s/he has an ear infection, and if still needed later on have tubes placed if s/he keeps on having recurrent ear infections. We are not testing any new drugs or procedures.
- If you decide to enroll your child in our study:
 - Our study team will examine your child every 8 weeks for 2 years, within 48 hours of any symptom suggestive of an ear infection, or when cold symptoms persist for at least 5 days.
 - At alternate visits (3 times each year), we will obtain a nose culture to check for resistant bacteria
 - When you child has an ear infection
 - We will take a picture of the ear drum.
 - S/he will be prescribed antibiotics (by mouth or topical ear drops, or both, depending on which treatment group your child is in), as we would routinely treat an ear infection. Treatment is not part of the study.
 - We will you send an email to complete a symptom diary on Days 1 through 5 and at Day 12.
- Children will have one final end-of-study visit 2 years after randomization.
- We will be available 24/7 to answer any questions you may have, and arrange for your child to be seen when you have any concerns.
- We will provide compensation for all study visits. (\$15)