

Ear infection superbug discovered to be resistant to all pediatric antibiotics

October 16 2007

Researchers have discovered a strain of bacteria resistant to all approved drugs used to fight ear infections in children, according to an article to be published tomorrow in the *Journal of the American Medical Association* (JAMA).

A pair of pediatricians discovered the strain because it is their standard practice to perform an uncommon procedure called tympanocentesis (ear tap) on children when several antibiotics fail to clear up their ear infections. The procedure involves puncturing the child's eardrum and draining fluid to relieve pressure and pain. Analyzing the drained fluid is the only way to describe the bacterial strain causing the infection.

Even after the ear tap and additional rounds of antibiotics, infections persisted in a small group of children in a Rochester, New York, pediatric practice, leading to ear tube surgery and, in one case, to permanent hearing loss. The physicians realized they may be dealing with a "superbug" and tested the children's ear tap fluid at the University of Rochester Medical Center. The tests showed that the superbug, called the 19A strain, could be killed only by an antibiotic (levofloxacin, Levaquin) approved for adults that had a warning in its label against use in children. With no other choice, they treated the children with crushed, adult-approved pills, and it worked.

The 19A strain was most likely created by a combination of the speed of bacterial evolution and the overprescribing of antibiotics, the authors said. They warn that, while it may very well never happen, the medical

profession must now at least consider the prospect of a worse-case scenario: this multi-drug-resistant bacterial ear infection spreads to other communities, or invades the lungs and bloodstream, where it leads to cases of pneumonia or meningitis treatable only with unconventional antibiotics not approved for use in children.

Experts have been arguing for years that pediatricians need to determine the type of bacteria causing an ear infection before “throwing an antibiotic at it.” Most do not know, nor are the later generations of doctors required to learn, tympanocentesis, the technique that makes that determination possible, according to the authors. The decision is made to treat with antibiotics regardless of whether the strain will clear up by itself, or whether the strain in question is resistant to the antibiotic used.

“Children with the new strain of superbug represented a small subset of those in our practice, but the results are worrisome, especially since there are no new antibiotics in the pipeline for ear infections in children,” said Michael Pichichero, M.D., professor of Microbiology, Immunology and Pediatrics at the University of Rochester Medical Center, and a partner at Legacy Pediatrics, the private practice involved. “While we must be careful not to create undue alarm, the potential exists for newly evolved strains to spread to the ears of more children,” said Pichichero, an author of the JAMA article.

Using an antibiotic not approved by the U.S. Food and Drug Administration (FDA) in children is a concern because the FDA makes certain that the drug is safe and effective before granting approval, Pichichero said.

The ‘off-label’ use of drugs like levofloxacin, a fluoroquinolone antibiotic, has been an area of intense debate because of potential safety issues, and because its excessive use in children, if it came about, may create resistance to the only drug effective against the superbug.

In the age of daycare, 83 percent of U.S. children experience one or more ear infections by age three. Acute otitis media is a bacterial ear infection that causes pain, fluid buildup and hearing loss in the worst cases. Until 2000, one species of bacteria, *S. pneumoniae*, also called pneumococcus, was the leading cause of otitis media, as well as of pneumonia and meningitis. Thanks to technology developed in part at the University of Rochester Medical Center, Wyeth Pharmaceuticals in 2000 introduced Prevnar (pneumococcal 7-valent conjugate vaccine), which reduced the incidence of pneumonia and meningitis by at least 69 percent, and difficult to treat ear infections by 24 percent as well, researchers said.

While tetanus is caused by a single strain of bacteria, *S. pneumoniae* seeks to evade the human immune system by coating itself in 90 variations of sugar capsule that mimic human cell coatings. Seven of these capsule variations, the most common in children and adults, were included in the 2000 version of Prevnar to create immunity against them. The 19A strain is named after its sugar capsule type, which is not among the seven in Prevnar. With the most common seven strains knocked down by Prevnar, the next several most common, including 19A, “filled the vacuum.” Physicians in the US then “barraged kids with antibiotics, often unnecessarily,” Pichichero said. That created evolutionary pressure in favor of the bacteria most able to resist antibiotics.

The 19A strain, for example, has developed resistance to every antibiotic approved by the FDA for use in children with ear infections (18 antibiotics). Having anticipated this problem, Wyeth began working on a vaccine that would also protect against the next six most common strains of *S. pneumoniae*, including 19A, almost as soon as it got approval for the original vaccine. Even if all goes well, however, the 13-strain vaccine is not expected before 2010.

In the current study, two pediatricians used tympanocentesis to identify *S*

pneumoniae strains that caused ear infections in children between September 2003 and June 2005. All the children had received the Prevnar vaccine. Among 1815 children, aged 6 to 36 months, in whom otitis media was diagnosed, tympanocentesis was performed in 212, yielding 59 cases of *S pneumoniae* infection and 9 cases infected with a serotype 19A strain resistant to all FDA-approved antibiotics for use in children. Of those nine, four required surgery to implant ear tubes after several attempts to treat with antibiotics failed. Levofloxacin was used in the next five cases, resolving the infection without surgery. Pichichero has published on the effectiveness and safety of quinolones in children with hard-to-treat ear infections, and the American Academy of Pediatrics endorsed their limited use where the benefits outweigh the risks, he said. Some past animal studies caused concern that the drug class may cause damage to weight-bearing joint cartilage in children, although such a side effect has not been observed in humans.

As expected, analyses of the ear tap samples over the three years revealed that those strains included in the original Prevnar vaccine were effectively prevented. But the study also found that strains not included in the vaccine have become more numerous in their place. In addition, the study showed that the strains not included in Prevnar at first were nearly all sensitive to most antibiotics, but over three years became dramatically more resistant to penicillin (from 25 to 93 percent of cases) (P

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