Bandaid immunization to prevent ear infections

Almost every child will develop an ear infection and unfortunately, some children will have seven or eight before their first birthday. These chronic infections can result in language, developmental and educational delays, all factors with long-term consequences. The best way to stop this cycle is to prevent the disease from even happening. A vaccine against ear infections could result in a reduction in antibiotic use, alleviate the child's ear pain and require less time off of work for the caretaker. Also, development of a way to non-invasively deliver the vaccine through the skin (called 'transcutaneous immunization') that does not require a needle jab could promote acceptance and allow for greater distribution of vaccines to children in parts of the world who do not have easy access to healthcare. Our strategy is to use a small, circular bandaid that is placed behind the ear.

Several vaccine components were tested in this study. Two of these vaccine candidates targeted nontypeable *Haemophilus influenzae*, a bacterium that causes a majority of cases of chronic ear infections. The third candidate targeted a protein that is critical for the bacteria to build a biofilm (a community of bacteria that is nearly impossible to eradicate with antibiotics) within the nose and ear. To immunize the animals in this study, vaccine formulations were placed on the gauze pad of a circular bandaid and then the bandaid was affixed to the skin behind the ear. Keeping the practicality of a bandaid remaining on a child in mind, we removed the bandaid after 24 hours. Another important aspect of this work is that we mimicked the disease course in children. Often, when a child is diagnosed with an ear infection, their parent reports that the child has had a cold a week earlier. We copied this time course by giving the animals a viral 'cold', then one week later inoculated them with bacteria. Then we looked in their ears every day for 28-30 days just as a doctor does when a child is taken to a clinic to see if there is fluid behind their ear drums. If there is, then that is an ear infection. If not, then the vaccine has prevented an ear infection.

We observed that immunization with a bandaid helped the immune system mount a local immune response that targeted the bacterial and biofilm proteins and ultimately prevented the bacteria from causing disease. This is the first time that bandaid immunization has been tested in an animal model that mimics the actual ear infection disease course observed in children. Immunization using a bandaid is a simple and highly effective strategy, and when combined with our vaccine candidates, has tremendous potential to reduce the burden of otitis media worldwide.

Laura A. Novotny [1], ***John D. Clements*** [2], ***Steven D. Goodman*** [1], ***Lauren O. Bakaletz*** [1]
[1]*Center for Microbial Pathogenesis, The Research Institute at Nationwide Children's Hospital and The Ohio State University College of Medicine, Columbus, Ohio, USA*
[2]*Department of Microbiology and Immunology, Tulane University School of Medicine, New Orleans, Louisiana, USA*

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Novotny LA, Clements JD, Goodman SD, Bakaletz LO

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