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Powdered measles vaccine found safe in early clinical trials

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A measles vaccine made of fine dry powder and delivered with a puff of air triggered no adverse side effects in early human testing and it is likely effective, according to a paper to be published November 28 in the journal *Vaccine*. The paper is now available online.

In 2013, measles killed 145,700 people, most of them children, according to the World Health Organization. That's despite the fact that the conventional injectable vaccine against the measles virus is effective.

"Delivering vaccines in the conventional way, with needle injections, poses some serious challenges, especially in resource-poor parts of the world," said Robert Sievers, co-author of the new paper, a fellow of the Cooperative Institute for Research in Environmental Sciences (CIRES) and also a professor in the University of Colorado Boulder's Department of Chemistry and Biochemistry.

His team innovated a dry delivery technique for the measles vaccine to eliminate the need for injections, liquid storage, and other challenges, such as vaccine contamination. "You don't need to worry about needles; you don't need to worry about reconstituting vaccines with clean water; you don't need to worry about disposal of sharps waste or other vaccine wastage issues; and dry delivery is cheaper," Sievers said.

The new paper represents the first successful Phase I clinical trial for a dry powder vaccine, he said. Sievers and his co-authors identified no adverse effects of the powdered and inhaled vaccine when tested in 60

healthy men who were already immune to measles. In this safety-focused clinical trial, they tested delivery with two devices—the Aktiv-Dry PuffHaler and BD Technologies Solovent—compared with the usual under-the-skin liquid injection method.

"Out of an abundance of caution, we test first in people who have already had the disease, or been injected earlier by needles with liquid vaccines," he explained. The men in all three groups responded similarly, with no clinically relevant side effects and some evidence of a positive immune response to vaccination. Because the men were already immune to the disease, this experiment could not yet compare effectiveness of the vaccines, measured by immune response. That will be the primary goal of follow-on Phase II/III pivotal trials.

"It is very good news that we encountered no problems, and now we can move on," Sievers said. The next phase of tests could include work in people who are not yet immune to measles, including women and children.

The authors of the new paper include researchers from the Serum Institute of India, Ltd., in Pune, India, which is the largest manufacturer of childhood vaccines used in developing countries; an Indian medical college; a North Carolina medical technology company; and the Georgia-based Centers for Disease Control and Prevention. Several of the authors also are affiliated with the Boulder company Aktiv-Dry, LLC, where Sievers is president and CEO.

In preclinical research, Sievers' team has already demonstrated that the vaccine protects rhesus macaques and cotton rats from infection by the measles virus. The researchers also have shown that their dry vaccines can be safely stored for 6 months to 4 years, at room temperature or in refrigerators kept at 36 to 46 degrees Fahrenheit (2-8 degrees Celsius), respectively.

More information: MVDP author group, Sharad Agarkhedkar, Prasad S. Kulkarni, Scott Winston, Robert Sievers, Rajeev M. Dhere, Bhagwat Gunale, Ken Powell, Paul A. Rota, Mark Papania, "Safety and immunogenicity of dry powder measles vaccine administered by inhalation: A randomized controlled Phase I clinical trial," *Vaccine*, Volume 32, Issue 50, 28 November 2014, Pages 6791-6797, ISSN 0264-410X, dx.doi.org/10.1016/j.vaccine.2014.09.071.