

Universal flu vaccine clinical trials show promise

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A universal influenza vaccine targeting a protein common to all strains of influenza A has safely produced an immune response in humans. If proven effective, the vaccine could eliminate the practice of creating a new flu vaccine annually to match predicted strains, with major implications for global health.

The results of the clinical trials, led by the University of Texas Medical Branch at Galveston in collaboration with <u>biotechnology company</u> VaxInnate and funded by \$9.5 million grant from the Bill and Melinda Gates Foundation, were published today online in the journal *Vaccine*.

The <u>vaccine candidate</u>, VAX102, targets a protein known as M2e, found on the surface of the <u>influenza A virus</u>, that has remained relatively unchanged over the last century. VAX102 consists of 4 copies of M2e fused to the protein flagellin, a TLR5 ligand used as an <u>adjuvant</u>. The M2e antigen had been completely unchanged from 1918 until the recent pandemic, making it of interest to researchers searching for a target for the <u>immune response</u> to influenza that would be stable over many seasons.

Unlike traditional flu vaccines, which target antigens that change continuously, the prototype VAX102 represents a vaccine that would not require annual updates, an important barrier to influenza prevention throughout the world. The technology used to produce the candidate vaccine would eliminate many of the limitations of current influenza vaccines, including inefficiencies related to manufacturing – such as



limited production capability and the inability to change the target antigen should the vaccine not match the circulating strains.

"As we saw in the 2009 influenza pandemic, there is a great public and global health need for a rapid, scalable model for vaccine production," said lead author Christine B. Turley, M.D., Vice Chair for Clinical Services, Department of Pediatrics and a member of UTMB's Sealy Center for Vaccine Development. "If ultimately proven effective, VAX102 will meet this need and offer a completely new approach to global flu prevention and control."

Two studies, conducted at UTMB and Johnson County Clin-Trials in Lenexa, Kansas, assessed the safety, tolerability and immunogenicity – the induced immune response – of VAX102.

Healthy adults ages 18-49 were randomly assigned to receive two doses of either vaccine or placebo. The two studies established the dose range for further study. Doses ranging from 0.03 to 10 micrograms were studied. Individuals at the highest doses had more systemic reactions; doses of 1 microgram or less were safe. All vaccinated subjects showed some degree of antibody response, with a more than four-fold increase noted in all groups by 14 days after the second dose of vaccine.

An important next step will be studies to determine the degree to which the vaccine may be effective against influenza infection. Future studies would also investigate the durability of the antibody response and more closely assess cytokine responses – proteins released as part of the immune response – in an effort to better understand, predict and potentially prevent the adverse reactions noted at highest doses.

Pending results of future trials, VAX102 could be used as a stand-alone vaccine to prevent influenza A infection. Other possible strategies include use in conjunction with vaccines that target traditional influenza



antigens, as a part of an approach to increase efficacy when infection occurs with mismatched strains.

VAX102 efficacy would have major global health implications, as worldwide annual influenza vaccination is not currently available due to limitations of licensed vaccines and international immunization infrastructure.

According to Turley, an <u>influenza vaccine</u> that can be produced rapidly and with great economies of scale, such as VAX102 through simple bacterial fermentation, allows for an entirely new approach to international influenza control. Further, because the M2e-based vaccine would not require annual updates, it could be useful to offer protection over multiple <u>influenza</u> seasons.

Finally, VAX102 holds promise as an improved vaccine for the elderly. "Our immune response deteriorates with age," said Turley. "Currently, the elderly aren't afforded as much protection from the <u>flu vaccine</u> as younger individuals. Rather than giving the elderly higher doses of a <u>vaccine</u> each year, VAX102 could afford long-term protection or be used as a booster strategy, maximizing immune memory."

Provided by University of Texas Medical Branch at Galveston

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