NIH awards $10 million to advance microneedle patch for flu vaccination

EurekAlert

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The National Institutes of Health (NIH) has awarded $10 million to the Georgia Institute of Technology, Emory University and PATH, a Seattle-based nonprofit organization, to advance a technology for the painless, self-administration of flu vaccine using patches containing tiny microneedles that dissolve into the skin.

The five-year grant will be used to address key technical issues and advance the microneedle patch through a Phase I clinical trial. The grant will also be used to compare the effectiveness of traditional intramuscular injection of flu vaccine against administration of vaccine into the skin using microneedle patches. In animals, vaccination with dissolving microneedles has been shown to provide immunization better than vaccination with hypodermic needles.

"We believe that this technology will increase the number of people being vaccinated, especially among the most susceptible populations of children and the elderly," said Mark Prausnitz, a professor in the Georgia Tech School of Chemical and Biomolecular Engineering, and the project's principal investigator. "If we can make it easier for people to be vaccinated and improve the effectiveness of the vaccine, we could significantly reduce the number of deaths caused every year by influenza."

Vaccine-delivery patches contain hundreds of micron-scale needles so small that they penetrate only the outer layers of skin. Their small size would allow vaccines to be administered without pain and could allow people to apply the patches themselves without visiting medical facilities.

While the ability to immunize large numbers of people without using trained medical personnel is a key advantage for the microneedle patch, the researchers have learned that administering the vaccine through the skin creates a different kind of immune response one that may protect vaccine recipients better.

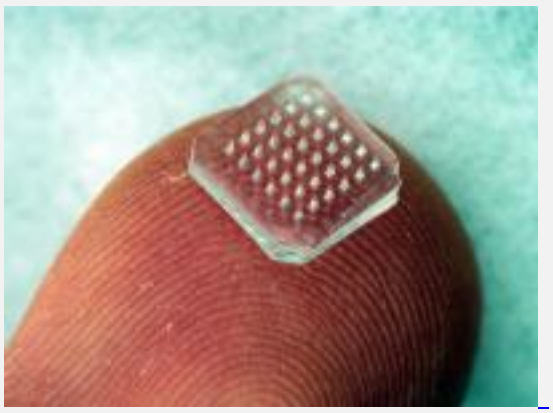
"We have seen evidence that the vaccine works even better when administered to the skin because of the plethora of antigen presenting cells which reside there," said Ioanna Skountzou, co-principal investigator for the project and an assistant professor in Emory University's Department of Microbiology and Immunology. "This study will allow us to determine how we can optimize the vaccine to take advantage of those cells that are important in generating the body's immune response."

Among the issues to be addressed in the five-year study are:

- Developing an administration system that will be simple to use, intuitive and reliable. "Our goal is to make these patches suitable for self-administration, so that anybody could take a patch out of an envelope, put it on, and have it work with high reliability," Prausnitz said.

- Studying the long-term stability of vaccine used in the patches, and optimizing technology for incorporating it into the dissolving microneedles. "We need to put the vaccine into a dry form in this patch," said Prausnitz. "That will require different processing than is normally done with vaccines. We expect that this dry vaccine will provide enough stability that the patches can be stored without refrigeration."

- Evaluating the economic, regulatory, social and medical implications of a self-administered vaccine. PATH, an international nonprofit organization, will assist with this work, and will help strategically address any issues. "We will be assessing the barriers that may exist to introduction of a self-administered flu vaccine so we can anticipate those issues and develop possible solutions," said Darin Zehrung, leader of the vaccine delivery technologies group at PATH.



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The funding will come from the Quantum program of the National Institute of Biomedical Imaging and Bioengineering (NBIB), which is part of the NIH. The initiative is designed to bring new medical technologies into clinical use.

While the funding focuses specifically on influenza vaccination, the lessons learned may advance other microneedle applications including vaccination efforts in developing countries where skilled medical personnel are limited and concerns

about re-use of hypodermic needles are significant.

Additional design and development of the microneedle patch will largely be done at Georgia Tech, with vaccine development, immunological studies and the Phase I trial carried out at Emory University. The trial, to be conducted by the Hope Clinic of the Emory Vaccine Center, is expected to take place during the final year of the grant, setting the stage for Phase II and Phase III clinical trials that would be required to obtain FDA approval.

Ultimately, the goal will be to produce an influenza vaccine delivery patch that could be made widely available. Prausnitz expects that will be done by an established company with the ability to manufacture and market the devices.

Microneedle drug and vaccine delivery systems have been under development at Georgia Tech and elsewhere since the 1990s. The technology got a significant boost in July of 2010 with publication of a study in Nature Medicine that showed mice vaccinated with dissolving microneedles were protected against influenza at least as well as mice immunized through traditional hypodermic needle injections.

The patches used in that study contained needles just 650 microns long, assembled into arrays of 100 needles. Pressed into the skin, the needles quickly dissolved into bodily fluids thanks to their hydrophilic polymer material, carrying the vaccine with them and leaving only a water-soluble backing. In contrast, use of hypodermic needles leaves the problem of "sharps" disposal.

Prausnitz hopes that the $10 million in NIH funding will help accelerate development of the microneedle patches to make them available for general use within five to ten years.

"This research will focus on optimizing the microneedle-based delivery of vaccines into the skin and understanding how this method affects immune responses both at the mucosal surfaces of the body and through the systemic response inside the body," added Skountzou. "Combined with the convenience of self-administration, painless application and absence of sharps waste, this novel immunization route could make the microneedle patch a powerful new weapon against infectious diseases."

SOURCE [3]

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