Students Devise Oral Quick-Dissolve Strips for Rotavirus Vaccine

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Unlike liquid formulas of rotavirus vaccine, the thin film would not need to be kept cool. This would reduce storage and distribution costs in developing nations. Photo by Will Kirk

A thin strip that dissolves in the mouth like a popular breath-freshener could someday provide life-saving rotavirus vaccine to infants in impoverished areas. The innovative drug-delivery system was developed by Johns Hopkins undergraduate biomedical engineering students.

During a two-semester course, the seven-student team fabricated a thin film that should melt quickly in a baby's mouth, prompting the child to swallow the vaccine. The dissolved medication is coated with a material to protect it in the child's stomach. This coating is also designed to release the vaccine in the small intestine, where it should trigger an immune response to prevent a rotavirus infection.

The novel drug-delivery system is needed because rotavirus is a common cause of severe diarrhea and vomiting in children, leading to about 600,000 deaths annually. Most of these occur in developing nations, where medical services to treat intestinal distress are not widely available. Rotavirus vaccine to prevent this illness is currently produced in a liquid or freeze-dried form that must be chilled for transport and storage, making it very expensive for use in impoverished areas. In addition, newborns sometimes spit out the liquid, a problem that is less likely to occur with a strip that sticks to and dissolves on the tongue in less than a minute.

To address the drawbacks of the liquid vaccine, the Johns Hopkins students developed a thin film delivery system that would be easy to store and transport and would not require refrigeration. Although further refinement is needed to maintain the viability of the vaccine, the delivery system itself appears sound, and the Johns Hopkins Technology Transfer staff has applied for a provisional patent. The thin film vaccine system was among the undergraduate projects introduced to the public this month at the university's annual Biomedical Engineering Design Day showcase.

"The idea is that you would place one of these dissolving strips on the infant's tongue," said Hai-Quan Mao, the team's Johns Hopkins faculty advisor. "Because the strips are in a solid form, they would cost much less to store and transport than the liquid vaccine. We wanted this to be as simple and as inexpensive as possible."

The idea originated last year at Aridis Pharmaceuticals, a San Jose, Calif., firm that possesses vaccine stabilization technologies and a rotavirus vaccine that is made stable at room temperatures. Seeking a product resembling breath-freshening strips to deliver the vaccine, Vu Truong, cofounder and chief scientific officer at Aridis, contacted Mao. Truong earned a doctorate in pharmacology and molecular science from the Johns Hopkins School of Medicine and knew of Mao's expertise in biomaterials. Mao, an assistant professor of materials science and engineering in the university's Whiting School of Engineering, described the vaccine challenge to one of his undergraduate lab assistants, senior Christopher Yu, who became co-leader of the team that tackled the project.

Initially, the students confronted several obstacles. They were unable to copy the manufacturing process used to make breath strips because the harsh solvent and high temperatures used would destroy the vaccine. They also had to devise a protective coating that would remain intact when exposed to stomach acid but would dissolve in the chemically neutral environment of the small intestine.

Through extensive research and testing, the students solved these problems. They refined a room-temperature production and drying process to make the strips and identified an FDA-approved biocompatible polymer coating that would protect the vaccine from stomach acid but release the medicine in the small intestine. The coating is pH-responsive, meaning it delivers its medical payload only when the acid-alkaline level in its environment is appropriate.

"What the students have accomplished is a way to incorporate a pH-responsive polymer system that works with an oral quick-dissolving thin film," Truong said. "It's still very early in the process, but the pieces they've come up with have been very encouraging. We have the delivery vehicle prototype. I'm optimistic that we can make this work with our vaccine."

Truong added, "I was pleasantly surprised. Professor Mao entrusted this project to some cream-of-the-crop students. They have delivered the kind of results that even seasoned professionals might not have delivered." Truong said his company is in talks to fund further research in Mao's lab to refine the strips so that they can dispense the Aridis rotavirus vaccine. Animal testing could begin later this year, he said. "This is probably the second-most important childhood vaccine needed in the developing world, right behind a malaria vaccine," he said. "The mortality rate is high."

The student inventors are pleased about the potential public health benefits. They also found the hands-on assignment to be a valuable part of their engineering education. "This was a really good experience," said Yu, the student co-team leader. "When you run into problems in a project like this, you have to think hard about how to solve them or work around them. It's much more rewarding than a basic textbook problem, where there's an expected answer and you don't necessarily have to think as broadly or as creatively."

Yu, who is from Shreveport, La., and the other team leader, Rohan Agrawal of Tampa, Fla., have been accepted into the biomedical engineering master's degree program at Johns Hopkins. The other members of the team were Yang Li, a senior from San Antonio, Texas; Dhanya Rangaraj, a junior from Foothill Ranch, Calif.; Jonathan Yen, a freshman from Hillsborough, Calif.; Shaoyi Zhang, a freshman from San Jose, Calif.; and Judy Qiu, a freshman from Potomac Falls, Va.

Source: Johns Hopkins University

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