

# Oral hepatitis B vaccine could become a reality

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In a new study, researchers report progress toward perfecting a radical new method of producing vaccines using genetically modified corn. The approach could lead to an oral hepatitis B vaccine that requires no refrigeration and costs less than \$1 per dose to manufacture.

"Even though an effective injectable hepatitis B vaccine was developed more than 30 years ago, high infection rates still persist in areas of the world where people cannot afford the vaccine or do not have reliable refrigeration," said John Howard, Ph.D., president of Applied Biotechnology Institute, which is developing the new vaccine. "This research brings us a step closer to vaccines that can be distributed throughout the world without refrigeration requirements as well as administered quickly and inexpensively."

Vaccines work by exposing a person to a harmless version of a pathogen that primes the immune system to recognize and eliminate the pathogen if the person is later exposed to its more dangerous form. Most vaccines used today are made by growing weakened or inactivated versions of pathogens in eggs.

The biotech firm Applied Biotechnology Institute developed a radically different approach in which corn is genetically modified to produce a non-infectious hepatitis B virus-like particle. Flour made from the corn grain can be added to sugar and water to make an edible wafer.

To learn how corn processing techniques might affect the vaccine's

properties, Applied Biotechnology Institute partnered with a research team led by Guru Rao, Ph.D., Roy J. Carver Professor at Iowa State University. After testing several methods for processing the corn, the Iowa State researchers found that using a separation technique known as supercritical fluid extraction to remove fat from the corn produced virus-like particles that most resembled those of injected vaccines. The corn-flour wafer produced with this processing method also showed up to a four-fold higher [immune response](#) in mice.

"Our work provides the first insight on how various methods of processing of plant material can affect the structure of the virus-like particles," said Shweta Shah, Ph.D., a staff scientist in Rao's lab who will present these findings at the American Society for Biochemistry and Molecular Biology (ASBMB) Annual Meeting during Experimental Biology 2015. "Processing affects the structure of the [virus-like particles](#) that are formed, as well as the efficacy of the vaccine."

The proteins and enzymes found in corn keep the vaccine stable, both when it is stored and shipped and after it is eaten, so it can reach the gut and activate an immune response. The vaccine can last for years at room temperature without losing strength. Because the corn-based vaccine is not injected and does not require purification like current vaccines, vaccine grain could be stored for long periods and then quickly and cheaply be turned into wafers when needed.

The raw materials for each wafer cost less than 1 cent, and the vaccine can be administered without medical staff. Howard estimates that the corn-based vaccine will cost less than 10 percent of what current injectable vaccines cost, even without taking into consideration the savings on refrigeration and medical staff.

The Applied Biotechnology Institute expects to receive FDA approval to start human trials of the corn-based hepatitis B vaccine within the next

year. If no problems arise, a commercial version of the [vaccine](#) could be available as early as 2018. Other types of vaccines could also be developed using the corn-based approach.

Hepatitis B is caused by a virus that attacks the liver. It can cause lifelong infection, cirrhosis of the liver, liver cancer, liver failure and death. In the U.S., approximately 1.2 million people have chronic hepatitis B, with an estimated 40,000 new cases each year. Worldwide, hepatitis B has infected nearly 2 billion people.

Provided by Federation of American Societies for Experimental Biology

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