

# Vaccines in fast-dissolving tablets

Novel product format to ensure vaccine effectiveness, affordability, and ease of use

## HEALTH NEED

Diarrheal disease is the second leading killer of children under the age of five and is responsible for 1.3 million child deaths annually.<sup>1</sup> It results from exposure to rotavirus as well as bacterial pathogens such as cholera, enterotoxigenic *E. Coli* (ETEC), and *Shigella*, among others. A number of live attenuated oral vaccines containing multiple bacterial strains are in development, giving hope to those that live in ETEC- and *Shigella*-endemic countries.

One challenge in the formulation of these new vaccines is that lyophilization (freeze drying) is required to obtain adequate stability. In addition, the individual strains are often incompatible and can only be combined when reconstituted at the point of use. If the vaccines are lyophilized in vials, then multiple vials containing each strain may be required alongside a vial for the diluent and a reconstitution syringe to combine them—increasing costs, cold chain space requirements, preparation complexity, and the risk of error. New formulation technologies are therefore needed to better address the technical challenges and costs associated with production, storage, transport, and delivery of these critical vaccines.

## TECHNOLOGY SOLUTION

PATH is developing fast-dissolving tablet (FDT) vaccine formulations that are manufactured using a standard lyophilization process. The small tablets are packaged in unit-dose blisters made from foil or other pharmaceutical-grade material, offering an inexpensive, scalable, and easy-to-use product presentation for live attenuated vaccines containing single or multiple bacterial strains.

There are two potential means of delivering the tablets. When placed in the mouth, the tablet vaccine disintegrates instantly in a small amount of saliva, removing the risk of choking and making it safe for use in young children. The tablets can also be reconstituted



PATH/Patrick McKern

in diluents or a buffer without need for a reconstitution syringe and then administered orally using a liquid dropper.

Due to less-expensive packaging material and an increased throughput achieved by lyophilizing smaller volumes, tablet vaccines may prove to be less expensive to produce than lyophilized vaccines in glass vials. The stackable product presentation also holds considerable promise. It may minimize product volume and thus the space required for storage and transport, resulting in significant savings from a health system and cold chain capacity perspective.

## APPLICATIONS

PATH scientists have successfully applied the FDT formulation to a trivalent live attenuated candidate ETEC vaccine. After evaluating a series of formulations and optimizing the freeze-drying parameters, PATH produced a lead FDT formulation that is stable for 12 months under refrigeration. Next steps will include developing an ETEC vaccine formulation that is stable at room temperature for four weeks in a glass vial format and adapting the candidate formulation into a tablet format. Additional

<sup>1</sup> United Nations Children's Fund, World Health Organization. Diarrhoea: Why Children Are Still Dying and What Can Be Done. New York, Geneva: UNICEF, WHO; 2009.

activities will involve scaling up and validating the production process for adoption by vaccine manufacturers. PATH is also applying the FDT technology to other vaccines, including a veterinary vaccine—with the goal of lowering production costs, enabling dosing size flexibility, expanding stability and reach, and increasing the ease of use of critical lifesaving vaccines.

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