

Blow-Fill-Seal Containers

Health need

There is an ongoing shift toward single-dose presentations for many vaccines and other pharmaceuticals, which can simplify administration (e.g., prefilled injection devices or prefilled squeeze tubes for oral delivery), improve safety, and reduce wastage of expensive vaccines or those that do not contain preservatives. However, single-dose containers pose challenges in low-resource settings, as they increase cost in comparison to multidose containers and can strain limited supply chain and waste disposal systems due to their larger size per dose. Alternative single-dose primary container formats that are low cost, easy to use, and minimize cold chain volumes could facilitate introduction of vaccines in single-dose presentations.

Technology solution

Blow-fill-seal (BFS) technologies use a polymer material to form the container. BFS is widely used for packaging of single-dose pharmaceuticals, but has yet to be introduced for vaccines. Blow molding combined with an aseptic filling process allows the manufacture, filling, and sealing of the container to be integrated into one production line. The BFS system therefore differs from other filling approaches, which typically require sterile containers to be produced and shipped to a pharmaceutical manufacturer for aseptic filling and finishing—adding cost and complexity.

The BFS manufacturing process can accommodate the filling of multiple containers into a single strip with a flexible detachment point, allowing for the easy separation of each unit-dose container at the point of delivery. A “multi-mono-dose” design of conjoined single-dose containers that are rendered open once removed from the shared label and strip could reduce manufacturing costs and minimize container volume.

Current status and results

PATH has evaluated and advanced the development of BFS containers for both oral and parenteral vaccines. We have developed a multi-mono-dose BFS container design for oral rotavirus vaccine, and evaluated compatibility with a vaccine candidate. A rotavirus vaccine in a multi-mono-dose BFS container is expected to be licensed in 2018. In collaboration with partners, we are also assessing potential designs for containers for parenteral vaccines. We have conducted evaluations in Ghana, Uganda, and Vietnam to obtain user and stakeholder feedback on BFS container designs, and completed cost modeling to quantify the potential impact of BFS and multi-mono-dose presentations on the cold chain and broader health care systems.



PATH

BFS container designs for oral and injectable vaccines.

“Blow-fill-seal technology could allow for single-dose presentations of vaccines, while minimizing the impact on the immunization supply chain and potentially lowering overall program delivery cost to allow for greater accessibility and availability for use in low-resource settings.”

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Availability

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