VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Blow-fill-seal primary containers

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Gavi The Vaccine Alliance

World Health Organization

BILL & MELINDA GATES foundation

PATH

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Blow-fill-seal (BFS) primary containers

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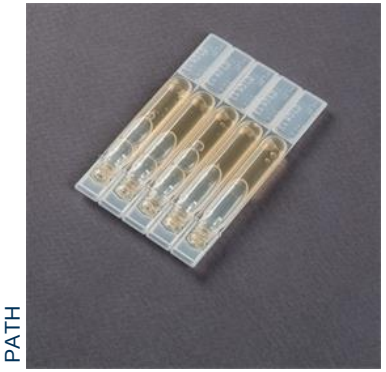
About BFS primary containers

- BFS is a single, continuous, aseptic filling process in which a polymer resin is melted, blown into a blister, filled with vaccine product, and sealed.
- BFS containers can be packaged either as separate single dose containers or conjoined as multi-mono-dose (MMD) containers.
- Two sub-types of single dose presentation primary container BFS have been assessed:
  - **Ampoule formats:** to withdraw the contents, the container **has to be opened by twisting off the top** of the container.
  - **Vial formats:** contents are withdrawn by inserting a needle and syringe through the septum.



Rommelag BFS ampoule

Rommelag BFS vial

Stage of development

- BFS containers are **widely used** to produce a variety of pharmaceuticals in polymer primary containers.
- GlaxoSmithKline's **oral rotavirus vaccine is available in a BFS 5-dose MMD strip** and Serum Institute of India, Pvt, Ltd uses **BFS ampoules for packaging diluent for their influenza vaccine**.

Blow-fill-seal (BFS) primary containers scorecard

Comparator: Single dose vial (SDV) (liquid vaccine)

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Quality of evidence: Moderate

VIPS Criteria		Indicators	Sub-types: Vial formats	Sub-types: Ampoule formats	Priority indicators - Country consultation: RI* Facility	RI* Community	Campaigns
Primary criteria	Health impact	Ability of the vaccine presentation to withstand heat exposure	Neutral	Neutral	+	++	++
		Ability of the vaccine presentation to withstand freeze exposure	Neutral	Neutral			
	Coverage & Equity impact	Ease of use [a]	Neutral	Neutral	+	+	++
		Potential to reduce stock outs [b]	Neutral	Neutral			
		Acceptability of the vaccine presentation to patients/caregivers	Neutral	Neutral		+	+
	Safety impact	Likelihood of contamination	Neutral	Worse			+
		Likelihood of needle stick injury	Neutral	Neutral			
	Economic costs	Total economic cost of storage and transportation of commodities per dose	Better	Better	+		
		Total economic cost of the time spent by staff per dose	Neutral	Neutral	++	++	+
		Total introduction and recurrent costs [c]	Neutral	Neutral			
Secon-dary criteria	Potential breadth of innovation use	Applicability of innovation to one or several types of vaccines	All liquid vaccines and diluents for dry vaccines are potential candidates.				
		Ability of the technology to facilitate novel vaccine combination	No				

* RI : Routine immunisation

++	Given significantly more importance
+	Given more importance
	Kept neutral

[a] Ease of use can prevent missed opportunities and impact ability for lesser trained personnel to administer the vaccine, including self-administration

[b] Based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities

[c] Total economic cost of one-time / upfront purchases or investments required to introduce the innovation and of recurrent costs associated with the innovation (not otherwise accounted for)

Blow-fill-seal (BFS) primary containers: Antigen applicability

- BFS primary containers could be applied to any liquid vaccine **administered parenterally**, or used for **diluents for dry vaccines**.
- Compatibility of a vaccine with the BFS filling process and material would have to be assessed on a case-by-case basis.
- Examples of VIPS priority antigens that would be **well-suited for a BFS primary containers are pentavalent and respiratory syncytial virus (RSV),** both currently available in single-dose presentations.

Blow-fill-seal (BFS) primary containers: Assessment outcomes

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KEY BENEFITS

✚ May **reduce storage and transportation costs:**

- Based on current prototype measurements, BFS primary containers have the potential to be **more compact** than single-dose glass vials.

- **Antigen applicability:**
  - Broad applicability to any liquid vaccine **administered parenterally**, or for **diluents for dry vaccines**.

KEY CHALLENGES

✚ Potential to **increase the risk of contamination:**

- Opening a **BFS ampoule** presentation could **expose the contents to the environment**.

- The cold-chain volume (compared with a vial) will be impacted by the space needed for product labelling, and whether an overwrap is required to prevent gas and water vapour ingress/egress through the polymer.

✚✚ Important attribute for at least 2 settings or for the 3 settings based on the country consultation (see slide 3)

✚ Important attribute for campaigns or routine facility-based immunisation based on country consultation (see slide 3)

Blow-fill-seal (BFS) primary containers: Rationale for prioritisation

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- Based on the analysis, BFS primary containers are included in a '**maybe**' category for prioritisation and **the Steering Committee is requested to provide advice on whether this innovation should be prioritised or not for Phase II.**
- While BFS primary containers **do not offer the health impact, coverage and equity, or safety benefits** of integrated primary containers like compact prefilled autodisable devices (CPADs), their **compact volumes could reduce delivery costs** and they have **broad applicability to all liquid, parenteral vaccines**.
- Since BFS containers are already used in the pharmaceutical industry, it is **unclear whether prioritisation by VIPS would add significant benefit**.

Additional important information to be analysed in phase II (if prioritised for Phase II)**:**

- Economic analyses of single dose and multi-mono-dose formats and the possibility of leveraging BFS manufacturing processes for other BFS products such as CPADs.
- Whether to prioritise BFS ampoules (sub-type) given the risks of contamination.
- The potential production, user handling, and disposal benefits of polymer containers versus glass.