VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Prefilled polymer blow-fill-seal droppers / dispensers

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Gavi The Vaccine Alliance

World Health Organization

BILL & MELINDA GATES foundation

PATH

unicef

Prefilled polymer blow-fill-seal (BFS) droppers / dispensers

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About prefilled polymer BFS droppers/dispensers

- Blow-fill-seal is an aseptic filling process that is **widely used** to produce a variety of pharmaceuticals in polymer primary containers.
- In BFS process, a polymer resin is melted into a parison, which is blown into a mould, filled, and sealed, all in a continuous process within a single piece of equipment. This is in contrast to preformed polymer squeeze tubes, in which the container is first produced and sterilized, and then shipped to a different site for filling and sealing.
- A BFS dropper produces metered-size droplets and **could be used for small dose volume vaccines such as oral polio vaccine (OPV)**, including multidose presentations. A BFS dispenser emits a stream of vaccine and could be used for oral vaccines such as rotavirus and cholera that typically have a larger dose volume.

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BFS squeeze tube dispensers (GSK Rotarix)

Stage of development

- BFS dispensers are **currently manufactured and commercially available**.
- In 2019, GlaxoSmithKline's (GSK's) **Rotarix oral rotavirus vaccine was the first vaccine to be WHO prequalified in a BFS container.**
- **Other vaccines are being evaluated for BFS dispenser** presentations.

Prefilled polymer blow-fill-seal (BFS) droppers / dispensers scorecard

Comparator: single dose vial (SDV) (liquid) and dropper/dispenser

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Quality of evidence: Moderate

VIPS Criteria		Indicators		Priority indicators - Country consultation: RI* Facility	RI* Community	Campaigns
Primary criteria	Health impact	Ability of the vaccine presentation to withstand heat exposure	Neutral	+	++	++
		Ability of the vaccine presentation to withstand freeze exposure	Neutral			
	Coverage & Equity impact	Ease of use [a]	Better	+	+	++
		Potential to reduce stock outs [b]	Better			
		Acceptability of the vaccine presentation to patients/caregivers	Neutral		+	+
	Safety impact	Likelihood of contamination	Better			+
		Likelihood of needle stick injury	Neutral			
	Economic costs	Total economic cost of storage and transportation of commodities per dose	Considerably better	+		
		Total economic cost of the time spent by staff per dose	Better	++	++	+
		Total introduction and recurrent costs [c]	Neutral			
Secon-dary criteria	Potential breadth of innovation use	Applicability of innovation to one or several types of vaccines	All liquid oral or intranasal vaccines are 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)

Prefilled polymer blow-fill-seal (BFS) droppers / dispensers: Antigen applicability

- BFS droppers/dispensers could be **used with liquid vaccines** that are **administered orally.**
- It is possible that vaccines that are **currently given as intranasal sprays could be given as intranasal drops using a BFS dropper.**
- 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 dropper/ dispenser include OPV, and liquid rotavirus**.
    - In 2019, GSK licensed a new presentation of Rotarix vaccine in a strip of 5 single-dose BFS squeeze tubes which **stacks to minimize the cold chain footprint.**

Prefilled polymer blow-fill-seal (BFS) droppers / dispensers: Assessment outcomes

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KEY BENEFITS

- **Potential to positively impact coverage and equity:**
  - ✚✚ May be **easier to use:**
    - Require **fewer preparation steps** than glass vials (which require a separate delivery device)
    - May **reduce errors and improve dose control**
  - Potential to **reduce stock-outs** due to fewer components required compared to a glass vial presentation (no need for a separate dropper device), simplifying distribution
- **May improve safety:**
  - ✚ Could reduce the **risk of contamination,** by reducing reuse of delivery device.
- **Potential to reduce economic costs:**
  - ✚ May **reduce storage and transportation costs** due to lower in the cold chain volume given the potential to be more compact than single-dose glass vials and out of cold chain volume due to fewer components
  - ✚✚ May **save health care worker time**

KEY CHALLENGES

- The space **saved in the cold-chain will be dependent on container design:**
  - How much space is required for product labelling, and whether an overwrap is required to prevent gas and water vapour ingress/egress through the polymer
- **Antigen applicability:**
  - Limited to oral and intranasal vaccines and diluents

✚✚ 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)

Prefilled polymer blow-fill-seal (BFS) droppers / dispensers: Rationale for prioritisation

- Based on the analysis, BFS droppers/dispensers 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 these devices offer benefits that could **positively impact coverage and equity and safety and reduce delivery costs, there are few VIPS priority vaccines that are delivered via the oral or intranasal route to which they apply.**
- In addition, 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 compact prefilled auto-disable devices (CPADs).
- The potential production, user handling, and disposal benefits of polymer containers versus glass.