VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Dual chamber vials

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Gavi The Vaccine Alliance

World Health Organization

BILL & MELINDA GATES foundation

PATH

unicef

Dual chamber vials

About dual chamber vials

- Dual-chamber vials are **integrated primary containers with a reconstitution feature.**
- They **contain both liquid and dry vaccine components**, which are mixed together within the device prior to administration which requires a separate delivery device.

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Dual chamber vial (Pfizer Act-O-Vial)

Stage of development

- Most dual-chamber technologies are at an **early stage of development**.
- **No vaccine products are currently approved for use** in dual-chamber vials, but some other pharmaceutical products are licensed in dual-chamber presentations, such as the Act-O-Vial which is used with Pfizer's Solu-Cortef and Solu-Medrol products (both glucocorticoids to treat allergic reactions and/or inflammation).
- Although some of these dual-chamber technologies **are available for market use, they would need to be approved with a specific antigen**.
- Preliminary research with some prototype devices has been carried out with vaccines.

Dual chamber vials scorecard

Comparator: Single dose vial (lyophilised) + diluent + reuse prevention (RUP) reconstitution needle and syringe (N&S)

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Quality of evidence: Low to 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	Better		+	+
	Safety impact	Likelihood of contamination	Better			+
		Likelihood of needle stick injury	Better			
	Economic costs	Total economic cost of storage and transportation of commodities per dose	Mixed	+		
		Total economic cost of the time spent by staff per dose	Better	++	++	+
		Total introduction and recurrent costs [c]	Neutral			
Secondary criteria	Potential breadth of innovation use	Applicability of innovation to one or several types of vaccines	Dry or other two-component vaccines, independent of route of delivery.			
		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)

Dual chamber vials: Antigen applicability

- Dual chamber vials could be **applied to all dry vaccine presentations that require reconstitution with a diluent**, or **other two-component vaccines that require mixing**.
- Examples of VIPS priority antigens that could be suitable **include MR and yellow fever**.

Dual chamber vials: Assessment outcomes

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KEY BENEFITS

- **Potential to positively impact coverage and equity:**
  - ✚✚ May be **easier to use: simplify and reduce the number of steps** involved in reconstitution of lyophilised vaccines, improving ease of use by the vaccinator.
    - Reduce mismatching and/or misallocation of vaccine components during distribution, potentially **reducing** vaccine and diluent **wastage and stock-outs and simplifying inventory processes**.
  - ✚✚ Potential to **increase acceptability: reduce the risk of reconstitution with the wrong diluent** which can lead to serious adverse events and have a negative impact on confidence in immunisation programs

- ✚ **May improve safety:**
  - Potential to **reduce errors** such as using the incorrect volume or type of diluent and reduce the **risk of contamination.**
  - Potential to also **reduce needle stick injuries** by eliminating the need for a separate reconstitution syringe, reducing the number of sharps.

- ✚✚ May **save health care worker time** since the time required for vaccine preparation and delivery is expected to be reduced.

- **Broad applicability** to dry and other two-component vaccines.

KEY CHALLENGES

- ✚ **Increase packaging volume and cold chain storage and transportation costs**, since the diluent is stored in the cold chain with the vaccine.
  - However this may reduce the out of cold chain volume and associated costs.

- **Technical challenges need to be overcome** related to the mechanism of the reconstitution feature and maintaining the moisture barrier between components during storage.

✚✚ 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)

Dual chamber vials: Rationale for prioritisation

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- Dual chamber vials are **not recommended to be prioritised for further analysis under Phase II.** While they offer expected positive impacts on coverage and equity, safety, and economic cost of staff time, **their potential impact is not as great as that of dual chamber delivery devices** which we recommend to prioritise for further analysis under Phase II.
    - The dual-chamber delivery devices have a **built in vaccine delivery system** that offers **better dose control** as the vaccine product does not have to be withdrawn from a separate vial, whereas the dual chamber vials still uses a needle and syringe to withdraw the vaccine product. Removal of this additional step could **reduce programmatic errors during delivery process of the vaccine**.