VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Dual-chamber delivery devices

June 2019

Gavi The Vaccine Alliance | World Health Organization | Bill & Melinda Gates foundation | PATH | unicef

Dual-chamber delivery devices

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

About Dual-chamber delivery devices

- Dual chamber delivery devices are **fully integrated reconstitution technologies** that are prefilled with liquid and dry vaccine components, which are mixed within the device and administered.

Stage of development

- A wide variety of technologies are at various stages of development, **from early design stage through commercial availability.**
- **No vaccines are licensed** in dual chamber delivery devices.

www.pharmaceutical-networking.com [a]

Dual chamber syringe (Vetter Lyoject)

PharmaPan [b]

Dual chamber blister with frangible seal

Neopac [c]

Dual chamber blister with frangible seal

Gavi The Vaccine Alliance | World Health Organization | Bill & Melinda Gates foundation | PATH | unicef

[a] https://www.pharmaceutical-networking.com/vetter-dual-chamber-delivery-systems/ [b] https://www.pharmapan.com/sites/default/files/downloads/2017-10/PHARMAPAN_Dual_Chamber_Blister_1.1.pdf
[c] https://www.webpackaging.com/en/portals/webpac/assets/11138717/neopacs-fleximed-now-in-large-format/

Dual-chamber delivery devices scorecard

Comparator: Single dose vial, diluent, reuse prevention reconstitution needle and syringe (N&S) and autodisable (AD) N&S

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

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 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)

Dual-chamber delivery devices: Antigen applicability

- Dual-chamber delivery devices could be **applied to all dry vaccine presentations that require reconstitution with a diluent**, or **other two-component vaccines that require mixing**.
- Versions for oral or injectable delivery are being developed.
- Examples of VIPS priority antigens that could be **suitable include MR and yellow fever**.
- Dual-chamber delivery devices are **also well-suited for simplifying the preparation of vaccines with multiple components** and **complex preparation steps like ETEC** to reduce preparation errors.

Dual-chamber delivery devices: Assessment outcomes

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

KEY BENEFITS

- **Potential to positively impact coverage and equity:**
  - ✚✚ May be **easier to use:**
    - Simplify and **reduce the number of steps involved in reconstitution and delivery** of lyophilized vaccines.
    - **Improve dose control.**
  - 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 in the cold chain storage and transportation costs**, since the diluent is stored in the cold chain with the vaccine as well as the delivery device.
  - However this may reduce the out of cold chain volume and associated costs.
- **Autodisable features are not present** on many dual chamber delivery devices, and would need to be developed.
- Significant **technical challenges need to be overcome**, such as ensuring adequate mixing of the two components prior to delivery, and developing a moisture barrier between the liquid and dry components that is sufficiently impermeable to ensure the stability of the lyophilised component.

✚✚ 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 delivery devices: Rationale for prioritisation

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

- Dual chamber delivery devices are **recommended to be prioritised for further analysis under Phase II** given their expected **positive impacts on coverage and equity, safety, and economic cost of staff time as well as their broad applicability to dry** and **other two-component vaccines**.
- Ideally, compact devices could be investigated to help overcome some of the increased cold chain volume requirements.

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

- Technical feasibility of emerging devices.
- Manufacturability and filling equipment requirements.
- Economic analyses.