VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Compact prefilled auto-disable devices

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Gavi The Vaccine Alliance

World Health Organization

BILL & MELINDA GATES foundation

PATH

unicef

Compact prefilled auto-disable devices (CPADs)

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About CPADs

- CPADs are **integrated primary containers and injection devices prefilled with liquid vaccines**. They have design features to **prevent reuse** and **minimize the space required for storage and shipping.**

Three CPAD subtypes have been assessed:

- **Preformed CPADs:** Manufactured 'open' and supplied sterile and ready to fill/seal by the vaccine manufacturer.
- **Blow-fill-seal (BFS) CPADs:** Manufactured using BFS automated technology; produced, filled, and sealed in a continuous process. Pre-assembled (with needle attached) and user-assembled devices are under development.
- **Other CPAD types.**

Preformed CPAD (Uniject™)

BFS CPAD (Apiject)

Stage of development

- One preformed CPAD, **Uniject™, is commercially available**.
- Uniject™ presentations of **pentavalent , hepatitis B and tetanus toxoid vaccines were WHO prequalified** in 2006, 2004 and 2003 respectively. The pentavalent and tetanus toxoid products have been discontinued. Medroxyprogesterone acetate is also commercially available in Uniject™.
- **BFS and other CPADs are in design phases.**

Other CPAD (Easyject)

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[a] https://drugdeliverysystems.bd.com/products/prefillable-syringe-systems/vaccine-syringes/uniject-auto-disable-pre-fillable-injection-system
[b] http://injecto.eu/easyject/

Compact prefilled auto-disable devices (CPADs) scorecard

Comparator: Single dose vial (liquid) and autodisable needle and syringe

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			Quality of evidence:	Moderate to high	Low to moderate	Low to moderate	Low			
				Sub-types				Priority indicators - Country consultation		
VIPS Criteria			Indicators	Preformed CPAD	BFS Pre-assembled	BFS User-assembled	Other type	RI* Facility	RI* Community	Campaigns
Primary criteria	Health impact		Ability of the vaccine presentation to withstand heat exposure	Neutral	Neutral	Neutral	Neutral	+	++	++
			Ability of the vaccine presentation to withstand freeze exposure	Neutral	Neutral	Neutral	Neutral			
	Coverage & Equity impact		Ease of use [a]	Better	Better	Mixed	Better	+	+	++
			Potential to reduce stock outs [b]	Better	Better	Neutral	Better			
			Acceptability of the vaccine presentation to patients/caregivers	Considerably better	Better	Better	Neutral		+	+
	Safety impact		Likelihood of contamination	Better	Better	Mixed	Better			+
			Likelihood of needle stick injury	Better	Better	Better	Better			
	Economic costs		Total economic cost of storage and transportation of commodities per dose	Better	Better	Considerably better	Mixed	+		
			Total economic cost of the time spent by staff per dose	Better	Better	Better	Better	++	++	+
			Total introduction and recurrent costs [c]	Neutral	Neutral	Neutral	Neutral			
Secondary criteria	Potential breadth of innovation use		Applicability of innovation to one or several types of vaccines	All liquid, parenteral 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)

Compact prefilled auto-disable devices (CPADs): Antigen applicability

- CPADs could be applied to **any liquid parenteral vaccines**.
- CPADs may be most useful with vaccines that would benefit from a compact single-dose presentation, for instance, for **outreach settings**.
- In the case of blow-fill-seal (BFS) CPADs, compatibility of a vaccine with the BFS filling process and material would have to be assessed on a case-by-case basis.
- For all CPADs the compatibility of the vaccine with the materials and its stability in the CPAD would have to be demonstrated.
- **Hepatitis B vaccine** (a VIPS priority antigen) is **currently WHO prequalified for use in Uniject™** and **used for birth dose delivery in Indonesia**.
- **Pandemic influenza** is another example of a **potentially suitable VIPS priority antigen for packaging in a CPAD.**

Compact prefilled auto-disable devices (CPADs): Assessment outcomes

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KEY BENEFITS

- **Potential to positively impact coverage and equity:**
  - ✚✚ May be **easier to use:** require no preparation and may improve dose control
    - Potentially **suitable for use by lesser trained vaccinators.**
    - Could **enable alternative delivery scenarios.**
  - Potential to **reduce stock-outs:** there is **only one component to be procured, distributed, and tracked**, as CPADs integrate the container with delivery technology.
  - ✚✚ Data exist supporting **increased acceptability** of Uniject™ preformed CPADs by caregivers/vaccines.

✚ May **improve safety** by reducing **risk of contamination** and **needlestick injuries** since CPADs are pre-filled.

- **Potential to reduce overall delivery costs:**
  - ✚ May **reduce storage and transportation costs** given CPADs' small volumes.
  - ✚✚ May **save health care worker time** as easier to use.

- **Antigen applicability**
  - CPADs could be applied to all liquid, parenteral vaccines.

KEY CHALLENGES

✚✚ **User assembled blow-fill-seal (BFS) CPADs rated lower than comparator** for **ease or use** and **risk of contamination**, due to more components and a more complex preparation.

✚ Data on prototypes of **Other Types of CPADs** indicate a larger volume than the comparator resulting in **potential higher delivery costs.**

✚✚ 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)

Compact prefilled auto-disable devices (CPADs): Rationale for prioritisation

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CPADs are **recommended to be prioritised for further analysis under Phase II** given their **broad potential public health benefits, broad applicability to liquid parenteral vaccines, and proven benefits in facilitating vaccine outreach.**

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

- Economic analyses given the likely higher cost of goods for CPADs.
- Review of the specialised filling equipment required for different CPAD types as this is a key determinant of vaccine manufacturer adoption.
- Potential deprioritisation of user-assembled CPADs as their drawbacks may limit use scenarios.