VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Disposable-syringe jet injectors (DSJIs)

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Gavi The Vaccine Alliance

World Health Organization

BILL & MELINDA GATES foundation

PATH

unicef

Disposable-syringe jet injectors (DSJIs)

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About DSJIs

- DSJIs are devices that **deliver vaccines in a narrow, high-pressure liquid stream** that can **penetrate through tissue without the use of needles**.
- DSJIs consist of a **needle-free syringe**, **a filling adapter**, and **a reusable injector**.
- Some designs are manually powered through an internal spring, which is reset through either an integrated mechanism or a separate reset station.
- Two DSJI subtypes have been assessed:
  1. DSJIs for **subcutaneous (SC)** and **intramuscular (IM)** delivery.
  2. DSJIs for **intradermal (ID)** delivery.

PharmaJet

PharmaJet® Stratis (SC/IM)

PATH

PharmaJet® Tropis (ID)

Stage of development

- Several DSJI devices **have device regulatory clearances**.
- The **PharmaJet Stratis and Tropis devices are WHO prequalified.**

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Disposable-syringe jet injectors (DSJIs) scorecard

Comparators: SC/IM subtype is compared to autodisable (AD) needle & syringe (N&S); ID subtype is compared to Bacille Calmette-Guerin (BCG) AD N&S

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Quality of evidence: Moderate

VIPS Criteria		Indicators	Sub-types: Subcutaneous /Intramuscular delivery	Sub-types: Intradermal delivery	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]	Mixed	Mixed	+	+	++
		Potential to reduce stock outs [b]	Worse	Worse			
		Acceptability of the vaccine presentation to patients/caregivers	Better	Considerably better		+	+
	Safety impact	Likelihood of contamination	Worse	Worse			+
		Likelihood of needle stick injury	Better	Better			
	Economic costs	Total economic cost of storage and transportation of commodities per dose	Worse	Worse	+		
		Total economic cost of the time spent by staff per dose	Neutral	Better	++	++	+
		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 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)

Disposable-syringe jet injectors (DSJIs): Antigen applicability

- DSJIs are most likely to be suitable for **delivery of vaccines that do not contain reactogenic components**, such as adjuvants.
- DSJIs may also increase immunogenicity of nucleic acid vaccine candidates.
- Examples of VIPS priority antigens that would be **well-suited for DSJI (SC/IM) delivery include MR and yellow fever.**
  - Serum Institute of India's MMR vaccine (Tresivac-NF) is labelled for delivery with DSJI.
- Examples of VIPS priority antigens that would be **well-suited for DSJI (ID) delivery include IPV, and rabies.**
  - For IPV, a fractional dose delivered ID can stretch the vaccine supply through dose-sparing strategies during vaccine shortages.

Disposable-syringe jet injectors (DSJIs): Assessment outcomes

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KEY BENEFITS

✚✚ **Potential to increase acceptability**: ID DSJIs have been found to be more acceptable to vaccine recipients and caregivers as they can **reduce pain at the time of injection and needle phobia**.

- May **improve dose control** and more doses can be obtained from a vial**,** due to DSJIs filling method.
- Could **reduce the risk of needlestick injuries** and sharps waste, by eliminating the use of needles.

✚✚ **Potential to save health care worker time:** could save time required to give injections in **high-throughput settings such as fixed-post campaigns.**

- A shift to ID delivery using ID DSJIs can enable **dose-sparing and stretch vaccine supplies**.

KEY CHALLENGES

- **Rated lower than the comparator on some aspects of coverage and equity:**

✚✚ May reduce **ease of use**: due to **more components** (reusable handpiece and in some cases separate re-setting station) and require **more steps to prepare** for vaccination.

- **Unlikely to be suitable for house-to-house delivery** scenarios.
- Potential to **increase stock-outs** due to more components.
- **SC/IM DSJIs can be painful** for recipients and cause more local reactogenicity, particularly with adjuvanted vaccines.

✚ May **increase risk of contamination** due to potential of reuse of filling adapter.

✚ **Potential to increase storage and transportation costs:** May **increase out of cold chain volume** required per dose of vaccine (when used with single-dose vials).

- **Limited applicability:** not suitable for vaccines **containing reactogenic components**, such as adjuvants.
  - Reactogenic components increase local reactions, which may be unacceptable and/or pose a safety risk depending on the target population.

✚✚ 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)

Disposable-syringe jet injectors (DSJIs): Rationale for prioritisation

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- DSJIs are **not recommended to be prioritised** for further analysis under Phase II due to their **mixed results on coverage and equity, safety, and economic costs.**