

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

June 2019











Disposable-syringe jet injectors (DSJIs)



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.

Stage of development

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



PharmaJet® Stratis (SC/IM)



PharmaJet® Tropis (ID)









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



Quality of evidence: Moderate			Sub-types		Priority indicators - Country consultation		
VIPS Criteria		Indicators	Subcutaneous /Intramuscular delivery	Intradermal	RI* Facility	RI*	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	* RI : Rou	tine immunisat	
Secondary criteria	Potential breadth of innovation use	Applicability of innovation to one or several types of vaccines	All parenteral vaccines are potential candidates.		++	Given significantly more importance	
					+	Given more	importance
		Ability of the technology to facilitate novel vaccine combination	N	0		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

^cTotal 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)

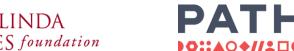
Disposable-syringe jet injectors (DSJIs): Antigen applicability



- 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



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 dosesparing 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.

Liportant 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



 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.







