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.
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

<table>
<thead>
<tr>
<th>VIPS Criteria</th>
<th>Indicators</th>
<th>Sub-types</th>
<th>Priority indicators - Country consultation</th>
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</thead>
<tbody>
<tr>
<td><strong>Quality of evidence: Moderate</strong></td>
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<tr>
<td><strong>Primary criteria</strong></td>
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<tr>
<td>Health impact</td>
<td>Ability of the vaccine presentation to withstand heat exposure</td>
<td>Neutral</td>
<td>+</td>
<td>++</td>
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<tr>
<td></td>
<td>Ability of the vaccine presentation to withstand freeze exposure</td>
<td>Neutral</td>
<td>+</td>
<td>++</td>
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<tr>
<td></td>
<td>Ease of use a</td>
<td>Mixed</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Potential to reduce stock outs b</td>
<td>Worse</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Acceptability of the vaccine presentation to patients/caregivers</td>
<td>Better</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Safety impact</td>
<td>Likelihood of contamination</td>
<td>Worse</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Likelihood of needle stick injury</td>
<td>Better</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Economic costs</td>
<td>Total economic cost of storage and transportation of commodities per dose</td>
<td>Worse</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Total economic cost of the time spent by staff per dose</td>
<td>Better</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Total introduction and recurrent costs c</td>
<td>Neutral</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td><strong>Secondary criteria</strong></td>
<td></td>
<td></td>
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<tr>
<td>Potential breadth of innovation use</td>
<td>Applicability of innovation to one or several types of vaccines</td>
<td>All parenteral vaccines are potential candidates.</td>
<td></td>
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<tr>
<td></td>
<td>Ability of the technology to facilitate novel vaccine combination</td>
<td>No</td>
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</table>

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

### KEY BENEFITS

1. **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.

2. **Potential to save healthcare 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.
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.