VIPS Phase I executive summary: Single-chamber cartridge injectors

June 2019
Single-chamber cartridge injectors

About single-chamber cartridge injectors

• **Vaccine delivery device** that has a needle and that **requires insertion of a prefilled cartridge of vaccine product.**

• Based on the design of the device, the **needle could be either exposed or not exposed.**

• Some cartridge injector devices have **auto-disable (AD) mechanisms** and/or **sharps injury protection (SIP) needle retraction mechanisms.**

Stage of development

• Currently all the single-chamber cartridge injector devices are **in the design or development phase** for use with vaccines.

• There are **no independent testing or user studies available** on the use of the devices in comparison to standard practice using the AD needle and syringe (N&S), and therefore no independent information exists on ease of use, time required to prepare and deliver, or cost and storage volume of the devices.

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\(^a\) Pradel G, Leader CT, Carestia S, Manager M. JUDO A new paradigm on compact and low cost vaccine delivery devices. 2017;

### Single-chamber cartridge injectors scorecard

**Comparator:** Single Dose Vial (SDV) liquid and Autodisable (AD) Needle and Syringe (N&S)

#### VIPS Criteria

<table>
<thead>
<tr>
<th>Primary criteria</th>
<th>Indicators</th>
<th></th>
<th>RI* Facility</th>
<th>RI* Community</th>
<th>Campaigns</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health impact</strong></td>
<td>Ability of the vaccine presentation to withstand heat exposure</td>
<td>Neutral</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Ability of the vaccine presentation to withstand freeze exposure</td>
<td>Neutral</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td><strong>Coverage &amp; Equity impact</strong></td>
<td>Ease of use</td>
<td>Better</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Potential to reduce stock outs</td>
<td>Neutral</td>
<td>+</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Acceptability of the vaccine presentation to patients/caregivers</td>
<td>Neutral</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td><strong>Safety impact</strong></td>
<td>Likelihood of contamination</td>
<td>Better</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Likelihood of needle stick injury</td>
<td>Better</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td><strong>Economic costs</strong></td>
<td>Total economic cost of storage and transportation of commodities per dose</td>
<td>Mixed</td>
<td>+</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>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Total introduction and recurrent costs</td>
<td>Neutral</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td><strong>Secondary criteria</strong></td>
<td>Applicability of innovation to one or several types of vaccines</td>
<td>All liquid, parenteral vaccines are potential candidates.</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Ability of the technology to facilitate novel vaccine combination</td>
<td>No</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
</tbody>
</table>

#### Priority indicators - Country consultation

- RI* : Routine immunisation

#### Quality of evidence: Low

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*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)
Single-chamber cartridge injectors: Antigen applicability

• Single-chamber cartridge injectors can be applied to any liquid parenteral vaccines.

• They may be most useful with vaccines that would benefit from a compact single-dose presentation such as RSV and pentavalent vaccines.
Single-chamber cartridge injectors: Assessment outcomes

**KEY BENEFITS**

- May be easier to use:
  - Removes the step of withdrawing vaccine from a vial which eliminates dosing errors and improves dose control.
  - Fewer and less complex preparation steps make vaccine preparation easier, in comparison to use of vials and AD N&S.

- May improve safety:
  - May reduce the risk of contamination, since single-chamber cartridge injectors use a pre-filled cartridge.
  - May reduce the risk of needle stick injuries and transmission of bloodborne pathogens, as some devices have sharps injury protection (SIP) features.

- May save health care worker time due to easier preparation steps.

- Broad applicability to all liquid parenteral vaccines.

**KEY CHALLENGES**

- May increase out of the cold chain volume and associated costs:
  - Glass cartridges have a smaller cold chain volume than single dose vials, but a single dose cartridge injector could be bulkier than an AD N&S, increasing the volume stored out of the cold-chain.

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)
Single-chamber cartridge injectors: Rationale for prioritisation

- Single chamber cartridge injectors are **not recommended to be prioritised** for further analysis under Phase II.

- While they have benefits in terms of ease of use, safety, and reduced preparation time, the benefits are not as great as those of compact prefilled autodisable devices (CPADs) which do not have out of the cold chain storage components, have greater ease of use advantages and the same broad applicability.