VIPS Phase I executive summary:
Dual-chamber delivery devices
June 2019
Dual-chamber delivery devices

About Dual-chamber delivery devices

• Dual chamber delivery devices are **fully integrated reconstitution technologies** that are prefilled with liquid and dry vaccine components, which are mixed within the device and administered.

Stage of development

• A wide variety of technologies are at various stages of development, **from early design stage through commercial availability.**

• **No vaccines are licensed** in dual chamber delivery devices.
**Dual-chamber delivery devices scorecard**

Comparator: Single dose vial, diluent, reuse prevention reconstitution needle and syringe (N&S) and autodisable (AD) N&S

**Quality of evidence:** Low to moderate

<table>
<thead>
<tr>
<th>VIPS Criteria</th>
<th>Indicators</th>
<th>Priority indicators - Country consultation</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Ability of the vaccine presentation to withstand heat exposure</td>
<td>RI* Facility: +, Community: ++, Campaigns: ++</td>
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<td></td>
<td>Ability of the vaccine presentation to withstand freeze exposure</td>
<td>RI* Facility: +, Community: ++, Campaigns: +</td>
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<tr>
<td>Health impact</td>
<td>Ease of use (^1)</td>
<td>Better</td>
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<tr>
<td></td>
<td>Potential to reduce stock outs (^2)</td>
<td>Better</td>
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<td></td>
<td>Acceptability of the vaccine presentation to patients/caregivers</td>
<td>Better</td>
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<tr>
<td>Coverage &amp;</td>
<td></td>
<td>RI* Facility: +, Community: +, Campaigns: +</td>
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<tr>
<td>Equity impact</td>
<td></td>
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<tr>
<td>Safety impact</td>
<td>Likelihood of contamination</td>
<td>Better</td>
</tr>
<tr>
<td></td>
<td>Likelihood of needle stick injury</td>
<td>Better</td>
</tr>
<tr>
<td>Economic costs</td>
<td>Total economic cost of storage and transportation of commodities per dose</td>
<td>RI* Facility: +, Community: ++, Campaigns: +</td>
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<tr>
<td></td>
<td>Total economic cost of the time spent by staff per dose</td>
<td>Better</td>
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<tr>
<td></td>
<td>Total introduction and recurrent costs (^3)</td>
<td>Neutral</td>
</tr>
<tr>
<td>Potential</td>
<td>Applicability of innovation to one or several types of vaccines</td>
<td>RI* Facility: ++, Community: ++, Campaigns: ++</td>
</tr>
<tr>
<td>breadth of</td>
<td>Ability of the technology to facilitate novel vaccine combination</td>
<td>Given significantly more importance</td>
</tr>
<tr>
<td>innovation use</td>
<td></td>
<td>Given more importance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kept neutral</td>
</tr>
</tbody>
</table>

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\(^1\) Ease of use can prevent missed opportunities and impact ability for lesser trained personnel to administer the vaccine, including self-administration

\(^2\) Based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities

\(^3\) 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)
Dual-chamber delivery devices:
Antigen applicability

• Dual-chamber delivery devices could be **applied to all dry vaccine presentations that require reconstitution with a diluent**, or other two-component vaccines that require mixing.

• Versions for oral or injectable delivery are being developed.

• Examples of VIPS priority antigens that could be **suitable include MR and yellow fever**.

• Dual-chamber delivery devices are **also well-suited for simplifying the preparation of vaccines with multiple components** and **complex preparation steps like ETEC** to reduce preparation errors.
Dual-chamber delivery devices: Assessment outcomes

**KEY BENEFITS**

- Potential to positively impact coverage and equity:
  - May be easier to use:
    - Simplify and **reduce the number of steps involved in reconstitution and delivery** of lyophilized vaccines.
    - Improve dose control.
    - Reduce mismatching and/or misallocation of vaccine components during distribution, potentially **reducing vaccine and diluent wastage and stock-outs and simplifying inventory processes**.
  - Potential to **increase acceptability**: reduce the risk of reconstitution with the **wrong diluent** which can lead to serious adverse events and have a negative impact on confidence in immunisation programs.

- May improve safety:
  - Potential to **reduce errors** such as using the incorrect volume or type of diluent and reduce the **risk of contamination**.
  - Potential to also **reduce needle stick injuries** by eliminating the need for a separate reconstitution syringe, reducing the number of sharps.
  - May **save health care worker time** since the time required for vaccine preparation and delivery is expected to be reduced.

- **Broad applicability** to dry and other two-component vaccines.

**KEY CHALLENGES**

- Increase packaging volume and in the cold chain storage and transportation costs, since the diluent is stored in the cold chain with the vaccine as well as the delivery device.
  - However this may reduce the out of cold chain volume and associated costs.

- **Autodisable features are not present** on many dual chamber delivery devices, and would need to be developed.

- Significant **technical challenges need to be overcome**, such as ensuring adequate mixing of the two components prior to delivery, and developing a moisture barrier between the liquid and dry components that is sufficiently impermeable to ensure the stability of the lyophilised component.

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)
Dual-chamber delivery devices: Rationale for prioritisation

- Dual chamber delivery devices are recommended to be prioritised for further analysis under Phase II given their expected positive impacts on coverage and equity, safety, and economic cost of staff time as well as their broad applicability to dry and other two-component vaccines.
- Ideally, compact devices could be investigated to help overcome some of the increased cold chain volume requirements.

Additional important information to be analysed in phase II (if prioritised for Phase II):
- Technical feasibility of emerging devices.
- Manufacturability and filling equipment requirements.
- Economic analyses.