VIPS Phase I executive summary: Bundling devices

June 2019
Bundling devices

About bundling devices
• Bundling devices allow vaccine components to be physically connected or placed together in the same secondary packaging to reduce the possibility of their separation and improve the likelihood of correct preparation and administration.

Stage of development
• Different formats of bundling devices are commercially available.
**Bundling devices scorecard**

Comparitor: Use without innovation (i.e. vaccine and diluent in separate packaging)

### VIPS Criteria

#### Health impact
- Ability of the vaccine presentation to withstand heat exposure
- Ability of the vaccine presentation to withstand freeze exposure

#### Coverage & Equity impact
- Ease of use
- Potential to reduce stock outs
- Acceptability of the vaccine presentation to patients/caregivers

#### Safety impact
- Likelihood of contamination
- Likelihood of needle stick injury

#### Economic costs
- Total economic cost of storage and transportation of commodities per dose
- Total economic cost of the time spent by staff per dose
- Total introduction and recurrent costs

#### Potential breadth of innovation use
- Applicability of innovation to one or several types of vaccines
- Ability of the technology to facilitate novel vaccine combination

### Indicators

<table>
<thead>
<tr>
<th>Priority indicators - Country consultation</th>
<th>RI Facility</th>
<th>RI Community</th>
<th>Campaigns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health impact</td>
<td>Neutral</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Coverage &amp; Equity impact</td>
<td>Better</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Safety impact</td>
<td>Neutral</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Economic costs</td>
<td>Mixed</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Potential breadth of innovation use</td>
<td>Neutral</td>
<td>++</td>
<td>+</td>
</tr>
</tbody>
</table>

* RI : Routine immunisation

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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)
Bundling devices: Antigen applicability

- Bundling devices could be applied to all vaccines that have more than one component required for preparation and delivery.
- Bundling devices can be used for packaging dry vaccines and their diluents to improve safety. Bundling reconstitution and delivery devices is also possible.
- MR is an example of a two-component vaccine that could benefit from bundling. ETEC is another potential candidate vaccine.
**Bundling devices: Assessment outcomes**

### KEY BENEFITS

- **Potential to positively impact coverage and equity:**
  - May be **easier to use: preparation is less complex**, since all vaccine components are provided in a single package.
  - Potential to **reduce stock-outs**: bundling devices reduce the number of separate vaccine product components to track throughout the supply chain, thus improving inventory management.
  - Potential to **increase acceptability**: Bundling devices can 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 **save health care worker time**:
    - The vaccinator saves time that would have been spent matching the vaccine and diluent.

- **Antigen applicability:**
  - Broad applicability to **all vaccines that have more than one component required for preparation and delivery.**

### KEY CHALLENGES

- **Rated lower than the comparator on some aspects of delivery costs:**
  - Might increase packaging volume, and cold chain storage and transportation costs, since the bundled components that would previously have been distributed outside the cold chain will now be stored and transported in the cold chain.
  - However this may reduce the out of cold chain volume and associated costs.

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**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)**
Bundling devices: Rationale for prioritisation

- Based on the analysis, bunding devices are included in a ‘maybe’ category for prioritisation and the Steering Committee is requested to provide advice on whether this innovation should be prioritised or not for Phase II.

- Bundling devices have been commercially available for many years and have benefits in terms of improving safety and ease of use and reducing stock-outs and health worker preparation time, however with the tradeoff of increasing in the cold chain volumes.

Additional important information to be analysed in phase II (if prioritised for Phase II):

- Analysis of priority vaccines for bundling for the purpose of market shaping.