VIPS Phase I executive summary: Plastic needles (for reconstitution)

June 2019
Plastic needles (for reconstitution)

About Plastic needles (for reconstitution)

• Polymer needles **designed to be capable of penetrating vial septums** could be used for reconstitution and access vaccine products.

• These needles could be designed to be attached to a reuse prevention (RUP) syringe or integrated into a RUP syringe itself.

Stage of development

• Plastic needles have **obtained regulatory approval as medical devices**.

• At present, there are **no commercially available reconstitution syringes with plastic needles**. However, there are prototypes available and commercial products could be adapted for this purpose.

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### Plastic needles (for reconstitution) scorecard

Comparator: Reuse prevention reconstitution (RUP) needle and syringe (N&S) with metal needle

#### VIPS Criteria

<table>
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<tr>
<th>Primary criteria</th>
<th>Indicators</th>
<th>Health impact</th>
<th>Coverage &amp; Equity impact</th>
<th>Safety impact</th>
<th>Economic costs</th>
<th>Secondary criteria</th>
<th>Potential breadth of innovation use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability of the vaccine presentation to withstand heat exposure</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
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<tr>
<td>Ability of the vaccine presentation to withstand freeze exposure</td>
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<td>Neutral</td>
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<td>Neutral</td>
<td>Neutral</td>
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<td>Ease of use</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
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<td>Potential to reduce stock outs</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
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<tr>
<td>Acceptability of the vaccine presentation to patients/caregivers</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
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<tr>
<td>Likelihood of contamination</td>
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<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
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<tr>
<td>Likelihood of needle stick injury</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Better</td>
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<tr>
<td>Total economic cost of storage and transportation of commodities per dose</td>
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<td>Neutral</td>
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<tr>
<td>Total economic cost of the time spent by staff per dose</td>
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<td>Neutral</td>
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<tr>
<td>Total introduction and recurrent costs</td>
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<tr>
<td>Applicability of innovation to one or several types of vaccines</td>
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<tr>
<td>Ability of the technology to facilitate novel vaccine combination</td>
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#### Priority indicators - Country consultation

<table>
<thead>
<tr>
<th>RI Facility</th>
<th>RI Community</th>
<th>Campaigns</th>
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#### VIPS Quality of evidence: Low

**RI**: Routine immunisation

**Comparator**: Plastic needles (for reconstitution) scorecard

- Plastic needles (for reconstitution) scorecard
- Comparator: Reuse prevention reconstitution (RUP) needle and syringe (N&S) with metal needle

**Indicators**

- **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

**Notes**:
- Ease of use can prevent missed opportunities and impact ability for lesser trained personnel to administer the vaccine, including self-administration
- Based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities
- 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)
Plastic needles (for reconstitution): Antigen applicability

• Plastic needles could be **applied to all dry formulation vaccines that require reconstitution with a diluent**, or **other two-component vaccines** in glass vials that require mixing.

• **MR and lyophilised presentations of MenACWY(X) are examples of two-component vaccines** that could use a plastic needle for reconstitution.
Plastic needles (for reconstitution): Assessment outcomes

**KEY BENEFITS**

- **May improve safety:**
  - Since plastic needles are less sharp than metal needles, they reduce the risk of needle-stick injuries during preparation or disposal.

- **Broad applicability** to all dry formulation vaccines that require reconstitution with a diluent, or other two-component vaccines in glass vials that require mixing.

**KEY CHALLENGES**

- **There are few technical challenges facing development of plastic needles, but limited benefits too.** They would only reduce the incidence of needle-stick injuries that occur during reconstitution, not after injection and would therefore not have an impact on transfer of blood-borne infections.

- Plastic needles have a wider bore than metal needles, and might therefore increase the risk of ‘coring’, whereby material from the septum becomes lodged in the needle cavity.
Plastic needles (for reconstitution): Rationale for prioritisation

- Plastic needles for reconstitution are **not recommended to be prioritised** for further analysis under Phase II given their **singular benefit** and the fact that **other innovations** under review by VIPS offer better ways to improve the reconstitution process.