VIPS Phase I executive summary: Intradermal (ID) Devices
June 2019
Intradermal (ID) Devices

About ID Devices

• ID devices and delivery devices used to inject vaccines into epidermal and dermal layers of the skin. They have been developed to improve the ease and accuracy of ID injections which are given at an acute angle to the skin to deposit the vaccine just below the surface (Mantoux technique).

• ID devices are grouped into three sub-types for this assessment:

1. Needle hubs and syringe adapters (with needles) that fit onto the end of luer syringes. They have an integrated short needle or needles (typically less than 1.5 mm) that only penetrate the skin to the depth of the dermis.

2. Syringe adapters (without needles) that attach to standard Bacille Calmette-Guerin (BCG) or insulin syringes with needles are designed to control the angle & depth of needle penetration.

3. Field-filled ID syringes that resemble a standard syringe but incorporate some form of needle (e.g. plastic needle) for filling and a short (less than 1.5 mm) needle for injection.

Stage of development

• Some ID devices have received regulatory approval as medical devices e.g. 510(k) in the USA or CE mark in Europe. One ID adapter and one needle-hub are available commercially.

• ID devices are not combination products and might not require approval with a specific vaccine from a named manufacturer.

• Several other devices are in very early stage of development and most/all of the devices in development do not include auto-disable (AD) features.

References:


# Intradermal (ID) devices scorecard

**Comparator:** Bacille Calmette-Guerin (BCG) autodisable (AD) needle and syringe (N&S) , using Mantoux technique

## VIPS Criteria

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

### Quality of evidence: Low to moderate

### 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)

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*RI*: Routine immunisation

Given significantly more importance

Given more importance

Kept neutral
Intradermal (ID) Devices: Antigen applicability

- ID devices could be applied to any vaccine that can be delivered intradermally, but vaccines formulated with adjuvants are less likely to be suitable.

- Examples of currently available vaccines that have been demonstrated to be compatible with ID delivery include: BCG, rabies, yellow fever, meningococcal conjugate vaccines and IPV.

- The live recombinant BCG ‘next-generation’ TB vaccine should also be suitable.

- ID devices may be most relevant as a dose-sparing strategy, to reduce the impact of supply or cost constraints.
## Intradermal (ID) Devices: Assessment outcomes

### KEY BENEFITS

- **Potential to increase acceptability:**
  - Injections with some ID devices are perceived as less painful.
  - ID devices are designed to serve as aids to improve injection accuracy (i.e., obtaining the appropriate angle and depth of injection) and therefore their use could potentially expand the number of HCWs available to deliver ID injections in a campaign setting.

### KEY CHALLENGES

- **Rated lower than the comparator on some aspects of coverage and equity:**
  - May reduce ease of use:
    - Existing data do not verify that the devices improve accuracy of ID injections among trained HCWs.
    - May increase risk of missed opportunities due to more components and more steps to prepare.
    - Potential to increase stock-outs due to more components (additional needles for filling, or separate syringe hubs, or separate adapters for fitting onto a syringe).

- **May negatively impact safety:**
  - Some ID-device designs could potentially increase the likelihood of contamination and needle-stick injuries due to additional preparation steps and lack of AD features.

- **May increase out of cold chain volume and storage and transportation costs** due to more components.

- **Limited applicability** since vaccines formulated with adjuvants are less likely to be suitable.

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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)**
Intradermal (ID) Devices: Rationale for prioritisation

- ID devices are **not recommended to be prioritised** for further analysis under Phase II given their limited benefits.

- While they do improve acceptability in comparison to standard BCG syringes using the Mantoux technique and may reduce training requirements, they come with many tradeoffs including added complexity and additional components that could negatively impact coverage and equity and safety. The ID needle hub also has **negative impacts on storage and delivery costs**.