VIPS Phase I executive summary: Microarray patches (MAPs)

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Microarray patches (MAPs)

About MAPs

• MAPs consists of an array of micro-projections on a patch.
• These micro-projections are coated with or are composed of vaccine in a dry formulation. When a MAP is applied to the skin, the vaccine is delivered into the dermis and/or epidermis layers.
• MAPs can be administered without an applicator, by applying pressure with fingers, or using an integrated applicator.a

Stage of development

• Various formats of MAPs are being developed for vaccine delivery by a number of different developers.
• Three developers have tested influenza vaccine MAPs in phase I clinical trials, and preclinical development is underway with other vaccines, including MR.
• MAPs for delivery of non-vaccine products, such as teriparatide (for osteoporosis) and Zolmitriptan (migraine) have been evaluated in phase II and III trials respectively.

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a Lead candidate MAPs for vaccine delivery either have no applicator or an integrated applicator. Therefore, MAPs with a separate applicator are not considered in this assessment.

b http://micronbiomedical.com/technology/
c https://www.who.int/immunization/research/meetings_workshops/PDVAC_2017_Delivery_Tech_Update_Zehrung_PATH.pdf?ua=1
Microarray patches (MAPs) scorecard
Comparators: Single dose vial (SDV) (liquid) and autodisable (AD) needle and syringe (N&S); SDV (lyophilised) + diluent + reuse prevention (RUP) reconstitution N&S and AD N&S.

Quality of evidence: Low

<table>
<thead>
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<th>VIPS Criteria</th>
<th>Indicators</th>
<th>Comparators</th>
<th>Priority indicators - Country consultation</th>
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<tbody>
<tr>
<td>Health impact</td>
<td>Ability of the vaccine presentation to withstand heat exposure</td>
<td>Better</td>
<td>++</td>
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<tr>
<td></td>
<td>Ability of the vaccine presentation to withstand freeze exposure</td>
<td>Better</td>
<td>+</td>
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<tr>
<td></td>
<td>Ease of use</td>
<td>Better</td>
<td>+</td>
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<tr>
<td></td>
<td>Potential to reduce stock outs</td>
<td>Better</td>
<td>++</td>
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<tr>
<td></td>
<td>Acceptability of the vaccine presentation to patients/caregivers</td>
<td>Considerably better</td>
<td>+</td>
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<tr>
<td>Coverage &amp; Equity impact</td>
<td>Likelihood of contamination</td>
<td>Better</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Likelihood of needle stick injury</td>
<td>Better</td>
<td>++</td>
</tr>
<tr>
<td>Safety impact</td>
<td>Total economic cost of storage and transportation of commodities per dose</td>
<td>Mixed</td>
<td>++</td>
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<tr>
<td></td>
<td>Total economic cost of the time spent by staff per dose</td>
<td>Better</td>
<td>++</td>
</tr>
<tr>
<td></td>
<td>Total introduction and recurrent costs</td>
<td>Neutral</td>
<td>++</td>
</tr>
<tr>
<td>Economic costs</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>Yes</td>
<td>++</td>
</tr>
</tbody>
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Primary criteria:
- Health impact
- Coverage & Equity impact
- Safety impact
- Economic costs
- Potential breadth of innovation use

Secondary criteria:
- Health impact
- Coverage & Equity impact
- Safety impact
- Economic costs
- Potential breadth of innovation use

Comparators:
- Liquid
- Lyophilised

RI*: Routine immunisation

Comparators:
- Single dose vial (SDV) (liquid) and autodisable (AD) needle and syringe (N&S)
- SDV (lyophilised) + diluent + reuse prevention (RUP) reconstitution N&S and AD N&S.

Priority indicators - Country consultation:
- ++ Given significantly more importance
- + Given more importance
- Kept neutral

* 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)
Microarray patches (MAPs): Antigen applicability

- MAPs could theoretically be developed to deliver any parenteral vaccine; however, each antigen must be individually assessed for compatibility; some antigens may not be stable or immunogenic in a MAP.

- The payload that can be delivered by a MAP might also limit which vaccines can be successfully used with this innovation.

- Local reactogenicity is expected to be greater than that seen with IM/SC injection, therefore vaccines that contain adjuvants might be unsuitable for MAPs.

- Examples of VIPS priority antigens that could be suitable include MR and rabies.
Microarray patches (MAPs): Assessment outcomes

**KEY BENEFITS**

- **Potential increased ability to withstand heat and freeze exposure** since MAPs require vaccines to be formulated into dry vaccines with low moisture content.

- **Potential to positively impact coverage and equity:**
  - May be **easier to use**: avoid the need for reconstitution and require less preparation
    - May **improve dose control and reduce errors**.
    - Potentially suitable for **use by lesser trained vaccinators** or **self-administration**.
    - Could **enable alternative delivery scenarios**.
  - Potential to **reduce stock-outs**: due to **fewer components** than injectable vaccines to be procured, distributed, and tracked.

- **Expected to be less painful** than needle and syringe, and data exist supporting **increased acceptability** by caregivers and vaccinees.

- **May improve safety**: could reduce the risk of contamination and needle-stick injuries/transmission of bloodborne pathogens, since MAPs avoid the need for reconstitution and do not have needles.

- **May save health care worker time** by eliminating the need for reconstitution.

- **Broad applicability to all parenteral vaccines and might facilitate novel vaccine combination:**
  - In theory, MAPs could allow combination of vaccines that cannot be co-formulated in a liquid or lyophilised formulation because the individual vaccine components could be loaded in/on different areas of the patch.

- MAPs might also result in **improved immunogenicity** so that fewer doses and/or less antigen per dose may be required for some antigens.

**KEY CHALLENGES**

- **Rated lower than the comparator on some aspects of delivery costs:**
  - Prototype designs suggest that MAPs would be **similar in size or larger than SDV** (especially if they have an integrated applicator), which could **increase cold chain storage and transport costs**.
  - However, MAPs without applicator or with an integrated applicator do not have any components stored out of the cold chain.

- **Minor local reactions lasting several days following application have been observed** in clinical studies; these were generally found to be acceptable however.

- 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)
Microarray patches (MAPs): Rationale for prioritisation

- MAPs are **recommended to be prioritised** for further analysis under Phase II given their **high potential positive impacts in the areas of health impact, coverage and equity, safety and their broad applicability.**

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

- Vaccine specific reviews of the public health value proposition.
- Review of technical readiness, commercial feasibility, and commodity costs.