VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Microarray patches (MAPs)

June 2019

Gavi The Vaccine Alliance

World Health Organization

BILL & MELINDA GATES foundation

PATH

unicef

Microarray patches (MAPs)

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About MAPs

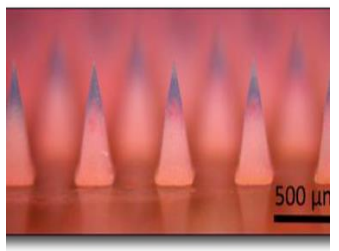
- MAPs consists of **an array of micro-projections on a patch**.
- These micro-projections are coated with or are composed of vaccine in a dry formulation. When a MAP is applied to the skin, the vaccine is delivered into the dermis and/or epidermis layers.
- MAPs can be administered **without an applicator**,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

Vaxxas, 15 May 2019

micronbiomedical.com [b]

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.



WHO [c]

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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.

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Quality of evidence: Low

VIPS Criteria		Indicators	Comparators: Liquid	Comparators: Lyophilised	Priority indicators - Country consultation: RI* Facility	RI* Community	Campaigns
Primary criteria	Health impact	Ability of the vaccine presentation to withstand heat exposure	Better	Better	+	++	++
		Ability of the vaccine presentation to withstand freeze exposure	Better	Neutral			
	Coverage & Equity impact	Ease of use [a]	Better	Better	+	+	++
		Potential to reduce stock outs [b]	Better	Better			
		Acceptability of the vaccine presentation to patients/caregivers	Considerably better	Considerably better		+	+
	Safety impact	Likelihood of contamination	Better	Better			+
		Likelihood of needle stick injury	Better	Better			
	Economic costs	Total economic cost of storage and transportation of commodities per dose	Mixed	Mixed	+		
		Total economic cost of the time spent by staff per dose	Better	Better	++	++	+
		Total introduction and recurrent costs [c]	Neutral	Neutral			
Secon-dary criteria	Potential breadth of innovation use	Applicability of innovation to one or several types of vaccines	All parenteral vaccines are potential candidates.				
		Ability of the technology to facilitate novel vaccine combination	Yes				

* RI : Routine immunisation

++	Given significantly more importance
+	Given more importance
	Kept neutral

[a] Ease of use can prevent missed opportunities and impact ability for lesser trained personnel to administer the vaccine, including self-administration

[b] Based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities

[c] 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

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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.