VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

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

June 2019

Gavi The Vaccine Alliance | World Health Organization | Bill & Melinda Gates foundation | PATH | unicef

Plastic needles (for reconstitution)

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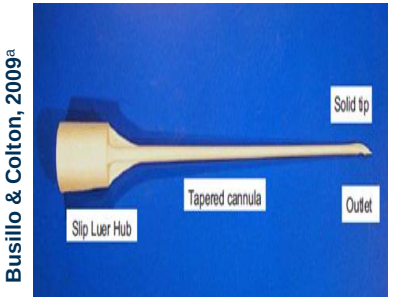
About Plastic needles (for reconstitution)

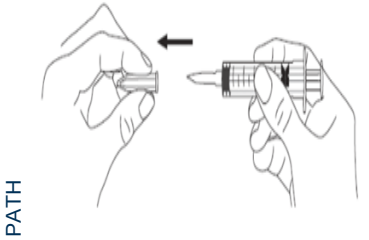
- Polymer needles **designed to be capable of penetrating vial septums** could be used for reconstitution and access vaccine products.
- These needles could be designed to be attached to a reuse prevention (RUP) syringe or integrated into a RUP syringe itself.



Plastic hypodermic needle

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.



K Spike Reconsitution syringe

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[a] Busillo E, Colton JS. Characterization of plastic hypodermic needles. J Med Device. 2009;3(4):41004.

Plastic needles (for reconstitution) scorecard

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

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Quality of evidence: Low

VIPS Criteria		Indicators		Priority indicators - Country consultation		
				RI* Facility	RI* Community	Campaigns
Primary criteria	Health impact	Ability of the vaccine presentation to withstand heat exposure	Neutral	+	++	++
		Ability of the vaccine presentation to withstand freeze exposure	Neutral			
	Coverage & Equity impact	Ease of use [a]	Neutral	+	+	++
		Potential to reduce stock outs [b]	Neutral			
		Acceptability of the vaccine presentation to patients/caregivers	Neutral		+	+
	Safety impact	Likelihood of contamination	Neutral			+
		Likelihood of needle stick injury	Better			
	Economic costs	Total economic cost of storage and transportation of commodities per dose	Neutral	+		
		Total economic cost of the time spent by staff per dose	Neutral	++	++	+
		Total introduction and recurrent costs [c]	Neutral			
Secondary criteria	Potential breadth of innovation use	Applicability of innovation to one or several types of vaccines	Dry or other two-component vaccines in a glass vial presentation.			
		Ability of the technology to facilitate novel vaccine combination	No			

* 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)

Plastic needles (for reconstitution): Antigen applicability

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- 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

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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

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- 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.**