

# VIPS Phase I executive summary: Bundling devices

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# Bundling devices

## About bundling devices

- Bundling devices allow vaccine components to be **physically connected** or **placed together** in the same secondary packaging to reduce the possibility of their separation and improve the likelihood of correct preparation and administration.

## Stage of development

- Different formats of bundling devices are **commercially available**.



PATH

Bundling clip connecting two vials



<https://cdn.vaccineingredients.net>

Preformed tray containing lyophilised vaccine, diluent and syringe

# Bundling devices scorecard

Comparator: Use without innovation (i.e. vaccine and diluent in separate packaging)



Quality of evidence: Moderate

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

\* RI : Routine immunisation

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

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

<sup>b</sup> Based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities

<sup>c</sup> 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)

# Bundling devices: Antigen applicability



- Bundling devices could be **applied to all vaccines that have more than one component required for preparation and delivery.**
- Bundling devices can be used for **packaging dry vaccines and their diluents to improve safety.** Bundling **reconstitution and delivery devices** is also possible.
- **MR** is an **example of a two-component vaccine that could benefit from bundling.** **ETEC** is another **potential candidate vaccine.**

# Bundling devices: Assessment outcomes



## KEY BENEFITS

- **Potential to positively impact coverage and equity:**
- ++ May be **easier to use: preparation is less complex**, since all vaccine components are provided in a single package.
  - Potential to **reduce stock-outs**: bundling devices **reduce the number of separate vaccine product components** to track throughout the supply chain, thus **improving inventory management**.
- ++ Potential to **increase acceptability**: Bundling devices can **reduce the risk of reconstitution with the wrong diluent** which can lead to serious adverse events and have a negative impact on confidence in immunisation programs.
- ++ May **save health care worker time**:
  - The vaccinator **saves time that would have been spent matching the vaccine and diluent**.
- **Antigen applicability**:
  - Broad applicability to **all vaccines that have more than one component required for preparation and delivery**.

## KEY CHALLENGES

- + **Rated lower than the comparator on some aspects of delivery costs**:
  - **Might increase packaging volume, and cold chain storage and transportation costs**, since the bundled components that would previously have been distributed outside the cold chain will now be stored and transported in the cold chain.
    - However this may **reduce the out of cold chain volume and associated costs**.

- ++ 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)

# Bundling devices: Rationale for prioritisation



- Based on the analysis, bundling devices are included in a **'maybe'** category for prioritisation and **the Steering Committee is requested to provide advice on whether this innovation should be prioritised or not for Phase II.**
- Bundling devices have been commercially available for many years and have benefits in terms of **improving safety and ease of use and reducing stock-outs and health worker preparation time**, however with the tradeoff of increasing in the cold chain volumes.

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

- Analysis of priority vaccines for bundling for the purpose of market shaping.