VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

# VIPS Phase I executive summary: Reconstitution vial adapters

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

# Reconstitution vial adapters

## About Reconstitution vial adapters

- Vial adapters can facilitate either:
  - **Vial to vial reconstitution using a reuse prevention (RUP) syringe without needle** for diluent transfer **(this sub-type is assessed in the TN);**
  - **Vial to vial reconstitution by directly connecting the two vials** without the use of a syringe for diluent transfer; or
  - **Reconstitution between a syringe prefilled with diluent and vaccine vial**. A prefilled syringe (without a fixed needle) containing the diluent is attached to the vaccine vial using the vial adapter as a connecting device. The diluent is then released into the vial through the vial adapter for mixing.
- Vial adapters are **manufactured in a variety of sizes**, and function by fitting over the top of a vial, while utilising a plastic spike to puncture the rubber stopper. Most designs are compatible with luer lock and luer slip syringes for liquid transfer.
- For oral or intranasal delivery, the delivery syringe can be connected to the vial adapter to draw the dose.
- For parenteral vaccines, the vial adapter would be removed after reconstitution and an autodisable (AD) needle and syringe (N&S) used to draw and inject the vaccine.

## Stage of development

- A variety of reconstitution vial adapters are **commercially available**.
- **ROTASIIL vaccine is supplied with a vial adapter for reconstitution** and drawing doses for oral delivery. The vaccine is a lyophilised (freeze-dried) presentation packaged in single-dose vials alongside a diluent.

West Pharmaceutical [a]

Vial adapters for reconstitution using a syringe

West Pharmaceutical [a]

Vial adapters for reconstitution using a syringe

West Pharmaceutical [b]

Vial adapters for direct vial to vial reconstitution

Serum Institute of India PVT. Ltd [c]


[a] https://www.westpharma.com/products/reconstitution-and-transfer-systems/vial-adapters
[b] https://www.westpharma.com/products/reconstitution-and-transfer-systems/mix2vial-and-needle-free-transfer-device
[c] https://www.google.com/search?q=Rotasiil+Rotavirus+Vaccine&hl=en&source=lnms&tbm=isch&sa=X&ved=0ahUKEwj-986zh-jgAhWFa1AKHbkdCucQ_AUIDigB&biw=1920&bih=861#imgrc=8XeGpeGcrBc7WM:&spf=1551687780860

# Reconstitution vial adapters scorecard

## Comparator: Use without innovation (i.e. reuse prevention reconstitution needle and syringe (N&S))

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**Quality of evidence:** Low to moderate

| 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] | Worse | + | + | ++ |
| | | Potential to reduce stock outs [b] | Worse | | | |
| | | Acceptability of the vaccine presentation to patients/caregivers | Neutral | | + | + |
| | Safety impact | Likelihood of contamination | Worse | | | + |
| | | Likelihood of needle stick injury | Better | | | |
| | Economic costs | Total economic cost of storage and transportation of commodities per dose | Worse | + | | |
| | | Total economic cost of the time spent by staff per dose | Worse | ++ | ++ | + |
| | | 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)

# **Reconstitution vial adapters:** Antigen applicability

- Reconstitution vial adapters could be **applied to all dry vaccine presentations 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 benefit from use of a vial adapter for reconstitution.

# **Reconstitution vial adapters:** Assessment outcomes

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## KEY BENEFITS

- **May** reduce the **risk of needle-stick injuries** during the preparation and reconstitution of dry vaccines, since reconstitution vial adapters are **sharps-free devices.**

- **Broad applicability** to all dry vaccines requiring reconstitution and other two-component vaccines in glass vials that require mixing.

## KEY CHALLENGES

- Rated **lower than comparator on some aspects of coverage and equity**:

✚✚ May **reduce ease of use**:
  - Require **more components and increase complexity**: use of the reconstitution vial adapters involves two components that are separately packaged (vial adapter and RUP syringe without needle) compared to standard practice which only requires one component (RUP syringe with needle).
  - May **increase stock-outs**, due to more components.

✚ May increase **risk of contamination** due to additional steps for vaccine preparation and the potential to reuse the reconstitution vial adapter.

- **May increase delivery costs:**

✚ May **increase out of cold chain volume and associated costs** due to the additional components.

✚✚ May **increase time spent by health care worker**, due to more complex preparation.

- Vial adapters 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.**

- The vial adapters have a wider bore than metal needles, and might therefore **increase the risk of 'coring'**, whereby material from the septum becomes lodged in the vial adapter cavity.

✚✚ 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)

# **Reconstitution vial adapters:** Rationale for prioritisation

- Reconstitution vial adapters are **not recommended to be prioritised** for further analysis under Phase II.
- Their single benefit in terms of reducing sharps injuries during reconstitution is **outweighed by multiple challenges negatively impacting coverage and equity, safety due to risk of contamination, and delivery costs**.
- In addition, **alternative innovations** to address reconstitution issues are being reviewed under VIPS that **offer greater potential benefits**., e.g. the dual chamber vials and delivery devices as well as other technologies that deliver products dry (including microarray patches, solid dose implants, fast dissolving tablets and sublingual dosage forms) and bundling devices (which improves use of the correct diluent).