VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

VIPS Phase I executive summary: Oral fast dissolving tablets

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

Oral fast dissolving tablets

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About Oral fast dissolving tablets (FDTs)

- Fast dissolving tablets are freeze **dried vaccine tablets** that **disintegrate rapidly in saliva.**
- Oral FDTs are **swallowed and rapidly disintegrate, delivering the vaccine to the gastrointestinal tract.**

CIMA [a]

Stage of development

- There are **several pharmaceutical companies** with drug products on the market **using a similar technology for producing oral FDTs.**
- Oral FDTs are in **preclinical development for vaccines such as ETEC.**

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[a] http://www.cimalabs.com/technology/lyoc.aspx

Oral fast dissolving tablets scorecard

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

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Quality of evidence: Low to Moderate

VIPS Criteria		Indicators	Comparators: SDV lyophilised + diluent + RUP + recon syringe and dropper	Comparators: SDV liquid + autodisable N&S	Priority indicators - Country consultation: RI* Facility	RI* Community	Campaigns
Primary criteria	Health impact	Ability of the vaccine presentation to withstand heat exposure	Neutral	Better	+	++	++
		Ability of the vaccine presentation to withstand freeze exposure	Neutral	Better			
	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	Neutral	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	Considerably Better	Considerably Better	+		
		Total economic cost of the time spent by staff per dose	Better	Better	++	++	+
		Total introduction and recurrent costs [c]	Neutral	Neutral			
Secondary criteria	Potential breadth of innovation use	Applicability of innovation to one or several types of vaccines	All vaccines against mucosal pathogens that be prepared in a dry format 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)

Oral fast dissolving tablets: Antigen applicability

- Oral fast dissolving tablets (FDT) **could be applied to vaccines that are intended for oral ingestion delivery.**
- All **vaccines against mucosal pathogens that can be lyophilised are potential candidates**.
- **Live vaccines against enteric pathogens are likely to be most suitable.**
- Non-live vaccines are likely to require a mucosal adjuvant, and none are approved at present.
- An oral FDT would be **particularly useful for ETEC vaccine** since the current presentation requires mixing of multiple components at the point of use.
- Oral FDT could also be **applied to oral live-attenuated rotavirus vaccine**.

Oral fast dissolving tablets: Assessment outcomes

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KEY BENEFITS

✚✚ May offer **improved heat stability and freeze resistance** over liquid vaccines given the **dried format.**

- **Potential positively impact on coverage and equity:**

✚✚ **Easy to use:** simplify preparation and delivery and may **reduce errors and improve dose control.**
  - Could **enable alternate delivery scenarios.**
  - May be **suitable for delivery by lesser-skilled health care workers.**

✚✚ Potential to **increase acceptability:** likely to be more acceptable due to the reduced pain of delivery.

- Potential to **reduce stock-outs** since the innovation has a **single component to be procured, distributed, and tracked.**

✚ May **improve safety** by reducing **risk of contamination** and **needlestick injuries**.

- **Potential to reduce overall delivery costs:**

✚ May **reduce storage and transportation costs** since FDTs are **extremely compact and eliminate the need to store and transport any components out of the cold chain.**

✚✚ May **save health care worker time**, as easy to use.

- **May facilitate novel vaccine combination:** vaccines for enteric pathogens often have incompatible components that could be produced as separate FDTs and delivered as separate tablets or diluted and delivered at the point of use.

KEY CHALLENGES

- **For infants and young children, FDTs need to be reconstituted** and administered with a liquid dropper/oral syringe to address the **potential risk of choking**, which negates some of the benefits for this age group.

- **Limited applicability** to vaccines against mucosal pathogens that can be lyophilised and live vaccines against enteric pathogens.
  - Applicability to **non-live vaccines is limited without the availability of a mucosal adjuvant.**

✚✚ 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)

Oral fast dissolving tablets: Rationale for prioritisation

- Based on the analysis, oral FDTs 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.**
- While the oral FDTs may yield high public health benefits, its **applicability to non-live vaccines is limited without the availability of a mucosal adjuvant and advancement of adjuvants** is outside of the purview of VIPS.

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

- Vaccine specific reviews of technical feasibility – especially for products requiring a mucosal adjuvant.
- Vaccine specific reviews of the public health value proposition – especially for products targeting younger age groups.