

VIPS - Vaccine Innovation Prioritisation Strategy

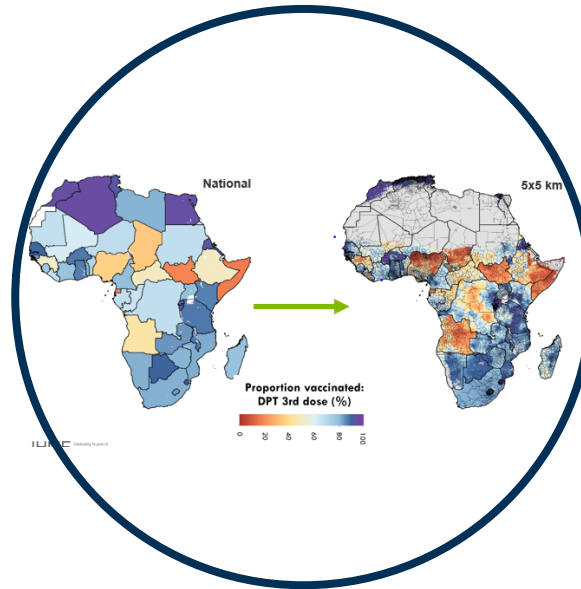
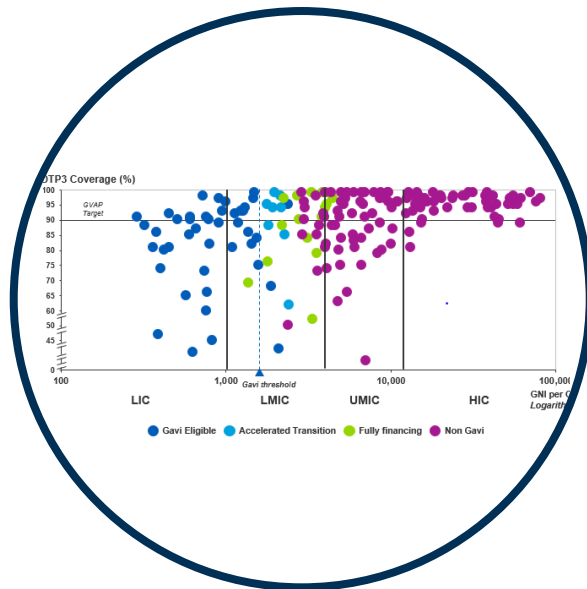
(focusing on vaccine delivery attributes)

Marion Menozzi-Arnaud, Gavi

Birgitte Giersing, WHO

October 2019

Why is VIPS needed?



Innovative delivery approaches will be needed to help achieve the Alliance coverage and equity targets

The next decade will likely need to shift to sub-national use of **differentiated products**

Many innovation initiatives across the Alliance, but strategy and effort **not coordinated or aligned**

VIPS background and goal



**2016 – 2020:
Innovation as one
of the Alliance
priorities for
shaping markets**

The Alliance aims to pursue a **common agenda of driving vaccine product innovation to better meet country needs and support Alliance goals**

Prioritise innovations in vaccine delivery attributes to provide greater clarity to manufacturers and immunisation partners to make investment decisions

VIPS

VIPS is a close Alliance-wide collaboration effort



BILL & MELINDA
GATES *foundation*



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GATES *foundation*



VIPS will be delivered through two prioritisation phases by end Q1 2020



December 2018 – June 2019

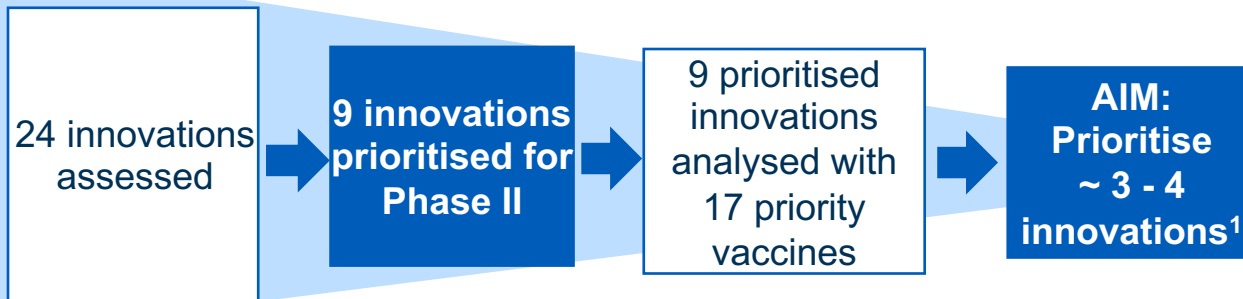
July 2019 – March 2020

Through 2020

Phase I: Initial prioritisation of innovations

Phase II: Final prioritisation of innovations paired with vaccines

Publication of a final report:



- Innovations' **characteristics** and **potential public health value**;
- **Potential 'breadth of use'** (applicability to several vaccines)

- Short-listed innovations **further analysed with priority vaccines**

- Process and methodology;
- **Most valuable innovations, rationale, recommendations;**
- Inform **research agenda**.
- **All assessments will be made public.**

¹ Purpose is to prioritise innovations "themselves", "as platforms", however it will be signaled for which individual vaccines or types of vaccines the innovation is seen to be most valuable.

24 vaccine product innovations are being assessed through the VIPS process



Primary vaccine containers (without delivery device)

- Blow-fill-seal (BFS) primary containers
- Dual chamber vials

Delivery technologies (not pre-filled)

- AD sharps-injury protection (SIP) syringes
- Disposable syringe jet injectors (DSJI)
- ID syringes

Integrated primary containers and delivery technologies

- Compact prefilled auto-disable devices (CPADs)
- Single-chamber cartridge injectors
- Dual-chamber delivery devices
- Microarray patches (MAPs)
- Prefilled polymer BFS dropper/dispensers
- Prefilled dry-powder intranasal devices
- Solid-dose implants (with applicator)
- Sub-lingual dosage forms
- Oral fast-dissolving tablets

Packaging and safety

- Bundling devices
- Reconstitution vial adapters
- Plastic needles (for reconstitution)

Labelling

- Freeze indicators on primary vaccine container
- Combined Vaccine vial Monitor (VVM) and Threshold Indicator (TI)
- Barcodes
- Radio Frequency Identification (RFID)

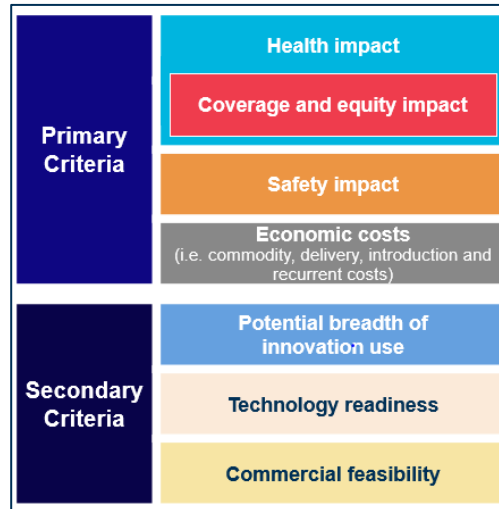
Formulation

- Heat stable/controlled temperature chain (CTC) qualified liquid formulations
- Heat stable/ CTC qualified dry formulations
- Freeze damage resistant liquid formulations

VIPS methodology relies on a thorough evaluation process, centered on country needs



VIPS advised by a
**Steering
Committee of 17
independent
experts** (9 are
members of
PDVAC or IPAC)



An **analytical
evaluation framework**
allows a **transparent
and balanced
assessment of
innovation benefits**

VIPS criteria		Phase I Indicators		RI facility community Campaigns		
Primary ranking criteria	Health impact	Ability of the vaccine presentation to withstand heat exposure	+	++	++	
		Ability of the vaccine presentation to withstand freeze exposure				
	Coverage & equity impact	Ease of use	+	+	++	
		Potential to reduce stock outs based on the number of separate components necessary to deliver the vaccine or improved ability to track vaccine commodities				
		Acceptability of the vaccine presentation to patients/caregivers		+	+	
	Safety impact	Likelihood of contamination			+	
		Likelihood of needle stick injury				
	Economic costs <i>(i.e. Delivery and Introduction and recurrent costs)</i>	Total economic cost of storage / transport of commodities per dose	+			
		Total economic cost of the time spent by staff per dose	++	++	+	
		Total economic cost of one-time / upfront purchases or investments required to introduce the vaccine presentation and of recurrent costs associated with the vaccine presentation (not otherwise accounted for)				
<div><div><input type="checkbox"/> ++ Give significantly more importance in evaluation</div><div><input type="checkbox"/> + Give more importance in evaluation</div><div><input type="checkbox"/> Keep weight neutral</div></div>						

Country consultations ensure that
country needs drive the prioritisation

VIPS methodology includes 3 country consultations



Understanding country immunisation barriers and needs

(that can be addressed by VIPS innovations)

- Online survey
- Q4 2018
- 500 complete responses across 55 Gavi and non Gavi countries

Identifying vaccine-specific barriers and needs

(that can be addressed by VIPS innovations)

- Online survey
- Q4 2019 - **Ongoing**

Feedback on 9 short-listed innovations under Phase I

- In-person in-depth interviews
- Q4 2019 - **Ongoing**
- 10-15 people in 5-7 countries at national and subnational levels

Inputs are used for weighting indicators to inform the prioritisation

Under Phase I, 9 innovations have been short-listed



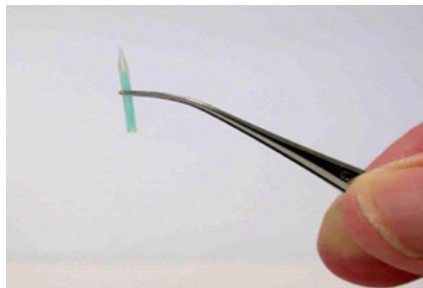
Microarray patches (MAPs)



Compact prefilled auto-disable devices (CPADs)



AD sharps-injury protection (SIP) syringes



Solid-dose implants



Dual-chamber delivery devices



Freeze damage resistant liquid formulations



Heat stable/controlled temperature chain (CTC) qualified liquid formulations



Combined Vaccine vial Monitor (VVM) and Threshold Indicator (TI)



Barcodes / Radio Frequency Identification (RFID)

Note: Innovation pictures are just examples of innovations

Priority vaccines for Phase II have been defined following a thorough process and validated by various stakeholders



Landscaping exercise	Primary inclusion criteria	Secondary inclusion criteria	Exclusion criteria
<ul style="list-style-type: none">• Long list of 48 vaccines• Characterised by route, formulation, presentation and delivery strategy	<ul style="list-style-type: none">• Coverage targets not met• Clear public health need¹• Pathogens likely to cause an outbreak• Target atypical population• Benefit from dose sparing• Standard MDV² with preservative not feasible	<ul style="list-style-type: none">• One vaccine per 'family'• Agenda for elimination/eradication• Unique delivery considerations• <u>Pipeline Vaccines:</u><ul style="list-style-type: none">• Robust pipeline• Most advanced candidate / high probability of success	<ul style="list-style-type: none">• <u>Licensed Vaccines:</u><ul style="list-style-type: none">• Not procured by UNICEF or PAHO• High income market driving development• Immunisation barriers not addressed by VIPS innovations• <u>Pipeline Vaccines:</u><ul style="list-style-type: none">• Vaccines for emergency response - except Ebola and pandemic influenza

17 vaccines prioritised, representative of the full vaccine landscape (administration route, formulation and presentation) - Validated by **IPAC, PDVAC, Gavi and VIPS SC**

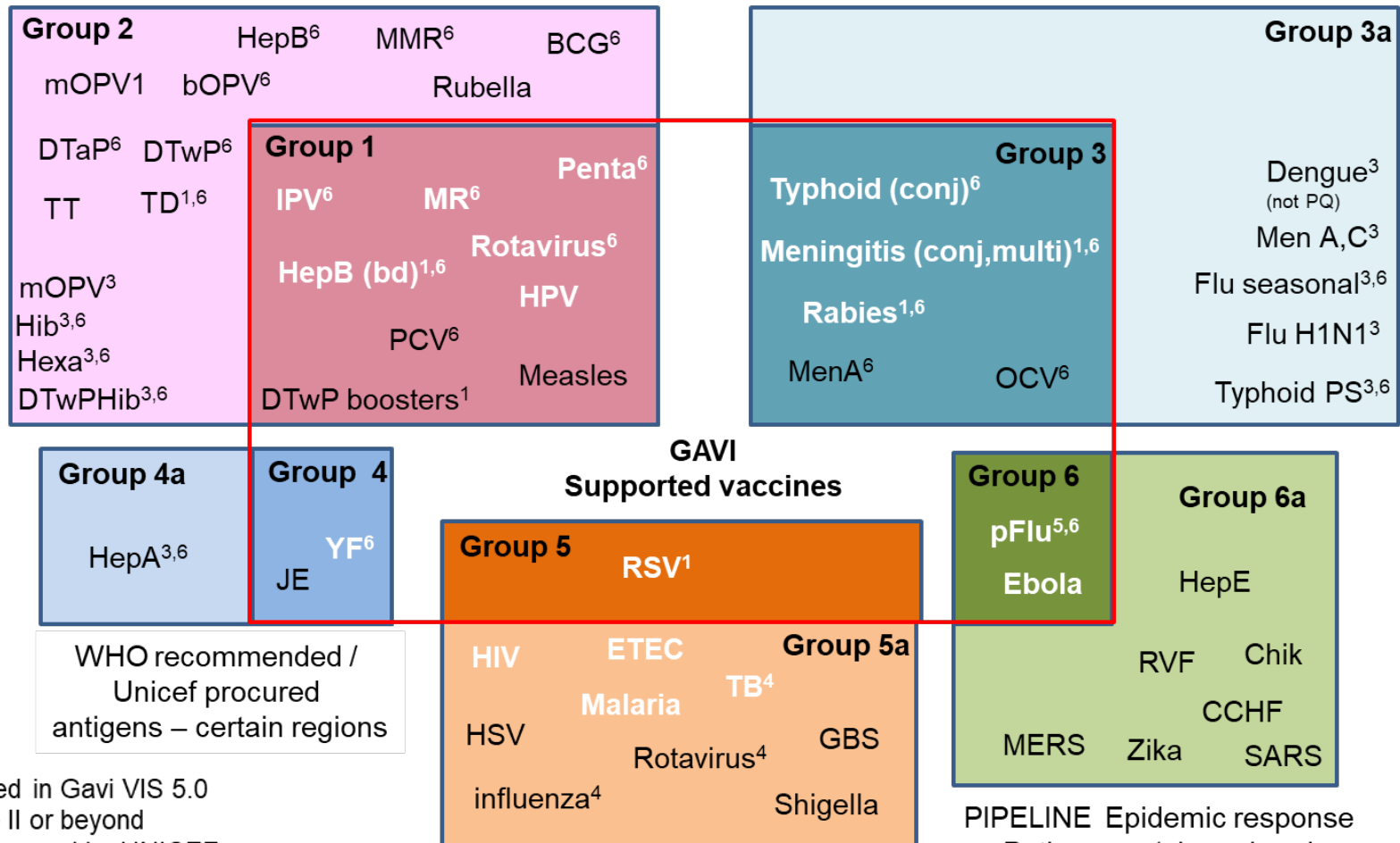
¹ As defined by vaccine preventable disease burden; ² Multi dose vial

Distribution of the 17 priority vaccines for Phase II within the landscape of 48 vaccines



WHO recommended / Unicef procured
antigens – routine immunization, all regions

WHO recommended / Unicef procured
antigens – high risk pops



KEY:

- 1 Included in Gavi VIS 5.0
- 2 Phase II or beyond
- 3 Not procured by UNICEF
- 4 Next generation
- 5 Gavi learning agenda
- 6 PAHO Revolving Fund

PIPELINE Priority antigens based on
BoD, unmet public health need
(phase II and beyond)

PIPELINE Epidemic response
Pathogens (phase I and
beyond)

Beyond countries, VIPS also ensures alignment and engagement with existing committees, industry and other initiatives



2018								2019												2020
Jun	Jul	Aug	Sep	Oct	Nov	Dec		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	H1

Short-list of innovations ▲ Final prioritised innovations ▲

WHO IPAC



WHO PDVAC



WHO DT-WG



SAGE

Other interested parties (e.g. CEPI, WT, etc.)



DCVMN



IFPMA



VIPS will also ensure alignment with other existing initiatives, e.g.

- Evaluation of *Full Public Value* for innovations
- Impact of innovations at the *systems level* within countries' immunisation programmes

Vaccine and technology developers/manufacturers

Inputs/Feedback from selected manufacturers/developers based on data questions and gaps

Updates upon request

VIPS aspirational vision – beyond Q1 2020



Beyond prioritisation and signalling, the Alliance recognises the need to support development and/or uptake of the prioritised innovations

Depending on Gavi 5.0 mandate and resources, **the Alliance will consider how to support the prioritised innovations beyond prioritisation and signalling**

Support may be needed for:

- **Product development**
- **Regulatory pathway**
- **Field studies**
- **Policy**
- **Procurement**
- **Implementation**
- **Etc.**

Questions for SAGE



- Does SAGE have any comments on the process that is being followed for prioritisation of innovations?
- Does SAGE wish to be further updated in the future?