VIPS - Vaccine Innovation Prioritisation Strategy
(focusing on vaccine delivery attributes)

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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 is a close Alliance-wide collaboration effort
VIPS will be delivered through two prioritisation phases by end Q1 2020

Phase I: Initial prioritisation of innovations

- 24 innovations assessed
- Innovations’ characteristics and potential public health value;
- Potential ‘breadth of use’ (applicability to several vaccines)

Phase II: Final prioritisation of innovations paired with vaccines

- 9 innovations prioritised for Phase II
- 9 prioritised innovations analysed with 17 priority vaccines
- AIM: Prioritise ~ 3 - 4 innovations

December 2018 – June 2019

July 2019 – March 2020

Through 2020

Publication of a final report:
- 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

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

**Packaging and safety**
- Bundling devices
- Reconstitution vial adapters
- Plastic needles (for reconstitution)

**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 advises 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. 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. 

<table>
<thead>
<tr>
<th>Landscaping exercise</th>
<th>Primary inclusion criteria</th>
<th>Secondary inclusion criteria</th>
<th>Exclusion criteria</th>
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</thead>
<tbody>
<tr>
<td>• Long list of 48 vaccines</td>
<td>• Coverage targets not met</td>
<td>• One vaccine per ‘family’</td>
<td>• Licensed Vaccines:</td>
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<tr>
<td>• Characterised by route, formulation, presentation and delivery strategy</td>
<td>• Clear public health need&lt;sup&gt;1&lt;/sup&gt;</td>
<td>• Agenda for elimination/eradication</td>
<td>• Not procured by UNICEF or PAHO</td>
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<td>• Pathogens likely to cause an outbreak</td>
<td>• Unique delivery considerations</td>
<td>• High income market driving development</td>
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<td>• Target atypical population</td>
<td>• Pipeline Vaccines:</td>
<td>• Immunisation barriers not addressed by VIPS innovations</td>
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<td></td>
<td>• Benefit from dose sparing</td>
<td>• Robust pipeline</td>
<td>• Pipeline Vaccines:</td>
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<td></td>
<td>• Standard MDV&lt;sup&gt;2&lt;/sup&gt; with preservative not feasible</td>
<td>• Most advanced candidate / high probability of success</td>
<td>• Vaccines for emergency response - except Ebola and pandemic influenza</td>
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</tbody>
</table>

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

<sup>1</sup> As defined by vaccine preventable disease burden; <sup>2</sup> 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**

- Group 2
  - HepB
  - MMR
  - BCG
  - mOPV1
  - bOPV
  - DTaP
  - DTwP
  - TT
  - TD
  - mOPV3
  - Hib
  - Hexa
  - DTwPHib

- Group 1
  - IPV
  - MR
  - Penta
  - HepB (bd)
  - Rotavirus
  - HPV
  - PCV
  - Measles
  - DTwP boosters

- Group 3
  - Typhoid (conj)
  - Meningitis (conj,multi)
  - Rabies
  - MenA
  - OCV

- Group 3a
  - Dengue
  - Men A,C
  - Flu seasonal
  - Flu H1N1
  - Typhoid PS

**WHO recommended / Unicef procured antigens – high risk pops**

**Group 4a**
- HepA

**Group 4**
- YF

**Group 4**
- JE

**Group 4a**
- YF

**Group 6**
- pFlu

**Group 6a**
- HepE

**Group 5**
- RSV

**Group 5a**
- HIV
- ETEC
- Malaria
- TB
- HSV
- Rotavirus
- GBS
- influenza
- Shigella

**Group 5**
- HIV
- ETEC
- Malaria
- TB
- HSV
- Rotavirus
- GBS
- influenza
- Shigella

**Group 6**
- pFlu

**Group 6a**
- HepE

**Group 6**
- RVF
- Chik
- CCHF
- MERS
- Zika
- SARS

**GAVI Supported vaccines**

**VIPS**

**Vaccine Innovation Prioritisation Strategy**

**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

**PIPEDLINE** Priority antigens based on BoD, unmet public health need (phase II and beyond)
Beyond countries, VIPS also ensures alignment and engagement with existing committees, industry and other initiatives.

<table>
<thead>
<tr>
<th>Short-list of innovations</th>
<th>Final prioritised innovations</th>
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- WHO IPAC
- WHO PDVAC
- WHO DT-WG
- SAGE
- Other interested parties (e.g. CEPI, WT, etc.)
- DCVMN
- IFPMA
- Vaccine and technology developers/manufacturers

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**

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

Updates upon request
VIPS aspirational vision – beyond
Q1 2020

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

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

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?