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Catalyzing product development of vaccine technology innovations: **Vaccine Innovation Prioritisation Strategy**

Marion Menozzi-Arnaud, Gavi

Debra Kristensen, PATH

Birgitte Giersing, WHO

October 2019



Catalyzing product development of vaccine technology innovations: Vaccine Innovation Prioritisation Strategy




Agenda

<i>Topic</i>	<i>Presenter</i>
• The Alliance VIPS initiative	Marion Menozzi, Gavi
• Nine prioritised innovations from the VIPS initial prioritisation phase	Debra Kristensen, PATH
• Process for the final prioritisation phase	Birgitte Giersing, WHO
• Q&A	Dr. Sotiris Missailidis
• Panel discussion - 'How VIPS may help drive vaccine delivery innovations but what else is needed beyond the prioritisation and communication?'	Dominic Hein, Gavi
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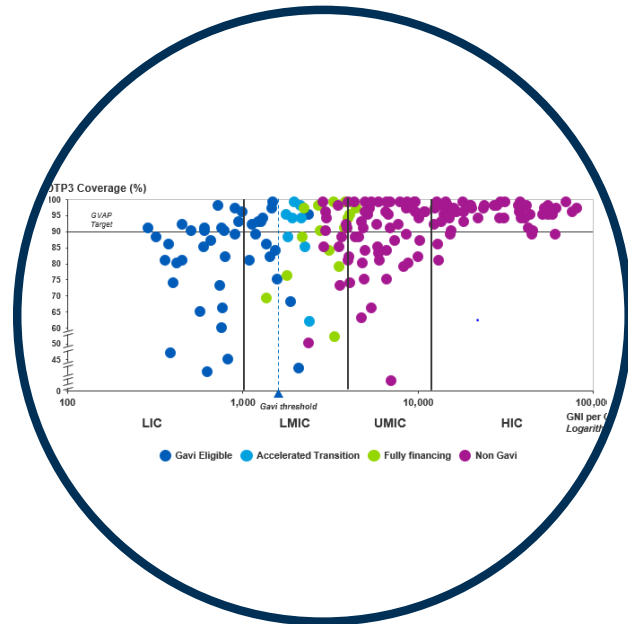
Catalyzing product development of vaccine technology innovations: Vaccine Innovation Prioritisation Strategy



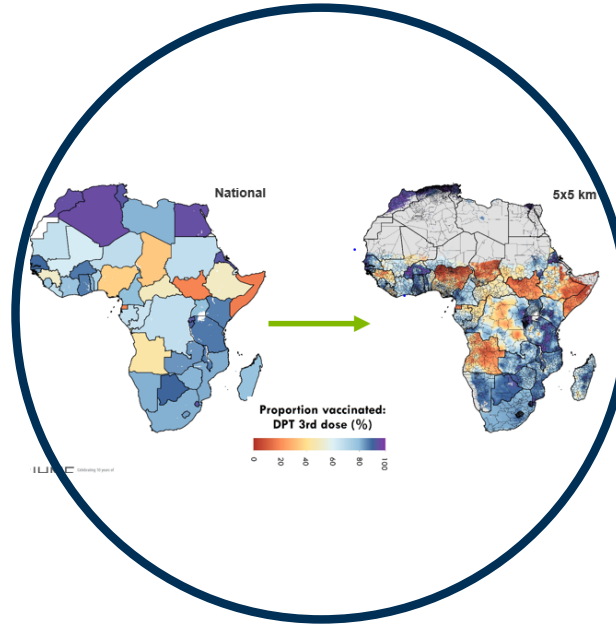
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Why is VIPS needed?



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 fully aligned or coordinated**

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



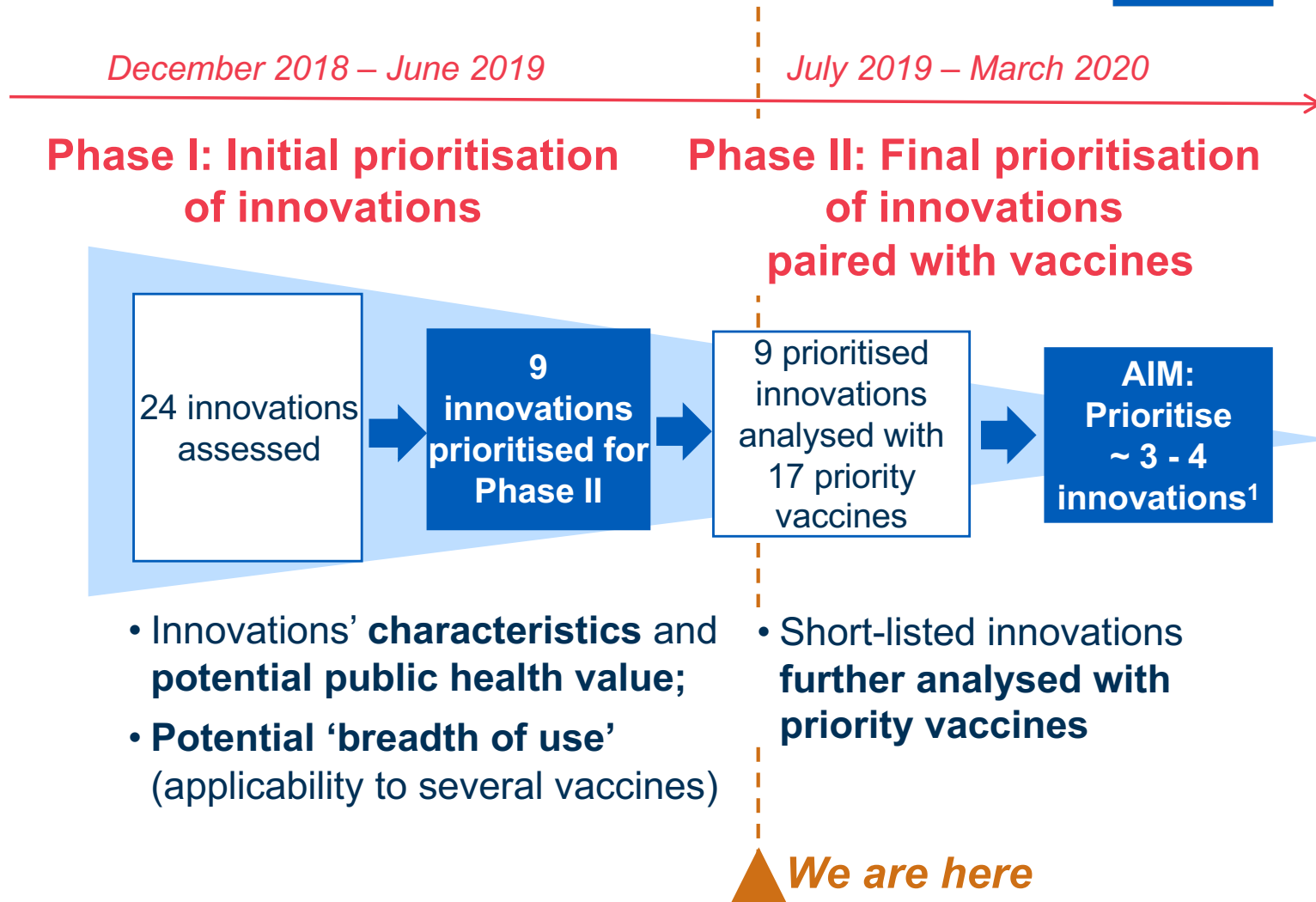
BILL & MELINDA
GATES *foundation*



BILL & MELINDA
GATES *foundation*



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



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 (CPAD)
- Single-chamber cartridge injectors
- Dual-chamber delivery devices
- Microarray patches (MAP)
- Prefilled polymer BFS droppers/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 on primary packaging

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

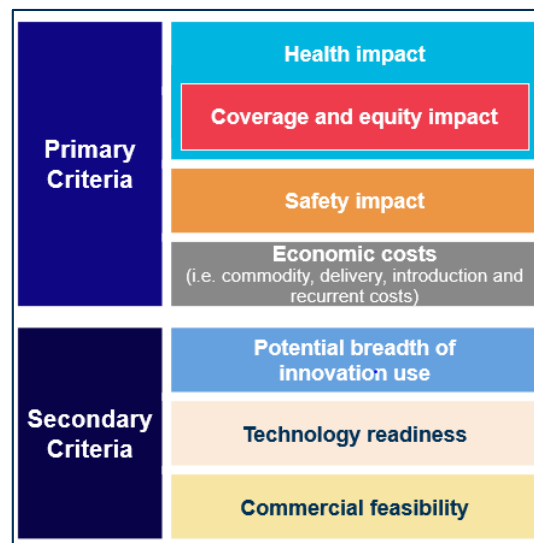
Formulation

- 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 WHO vaccine advisory committees (PDVAC and 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)				

++

Give significantly more importance in evaluation

+

Give more importance in evaluation

Keep weight neutral

Country consultations ensure that **country needs drive the prioritisation**



Evaluation framework for Phase I



Criteria

Indicators

Primary ranking criteria	Health Impact	<ul style="list-style-type: none"> • Ability of the innovation to withstand heat exposure • Ability of the innovation to withstand freeze exposure
	Coverage and Equity impact	<ul style="list-style-type: none"> • 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 innovation to patients/caregivers
	Safety impact	<ul style="list-style-type: none"> • Likelihood of contamination • Likelihood of needle-stick injury
	Economic costs (i.e. Delivery and Introduction and recurrent costs)	<ul style="list-style-type: none"> • Total cost of storage and transport of commodities per dose • Total cost of the time spent by staff per dose • Total cost of introduction and recurrent costs (not otherwise accounted for)
Secondary criteria	Potential breadth of innovation use	<ul style="list-style-type: none"> • Applicability of the innovation to one or several types of vaccines • Ability of the innovation to facilitate novel vaccine combination

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

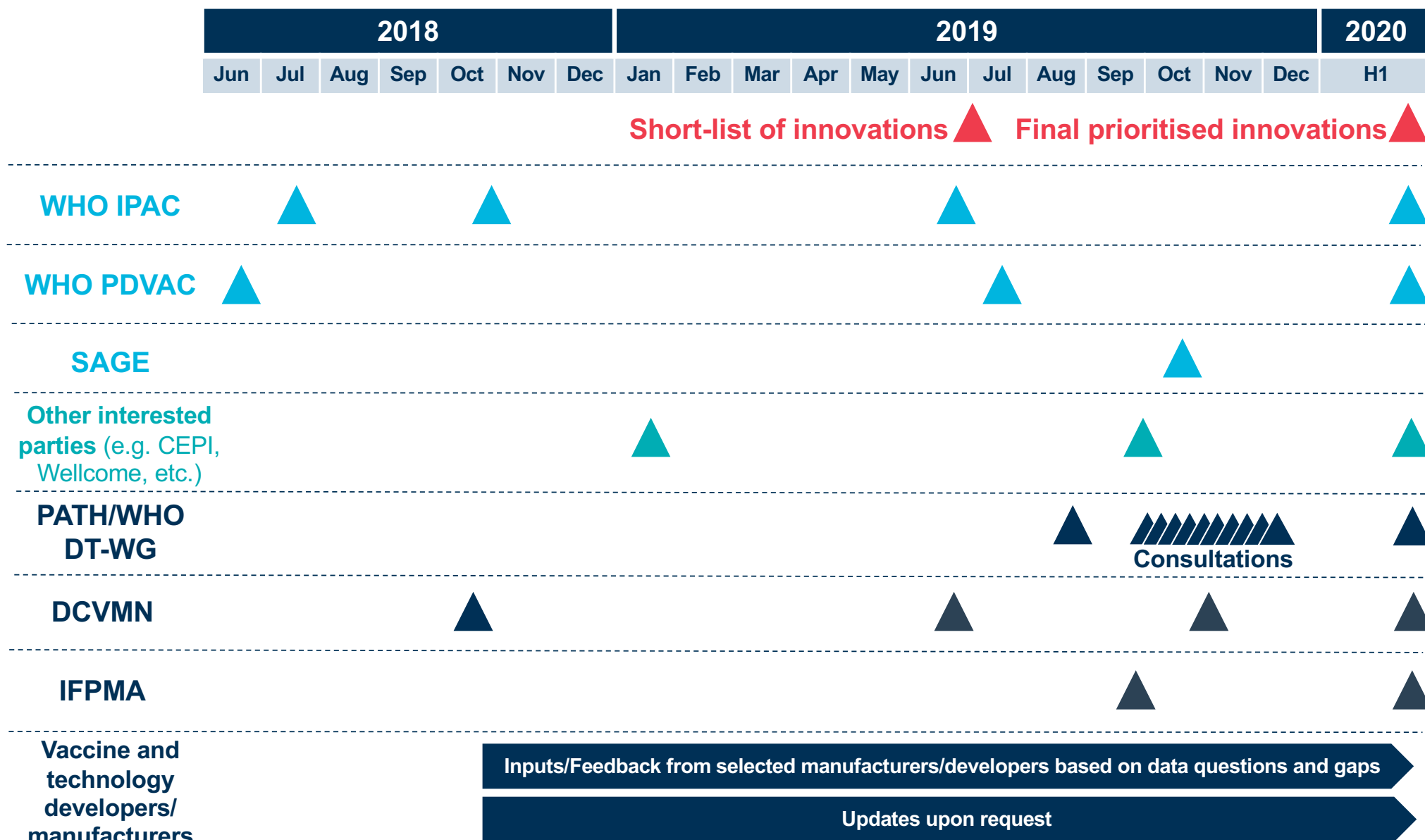
Feedback on 9 short-listed innovations under Phase I

- In-person in-depth interviews
- Q4 2019 - Ongoing
- 10-15 people in 5-6 countries at national and subnational levels

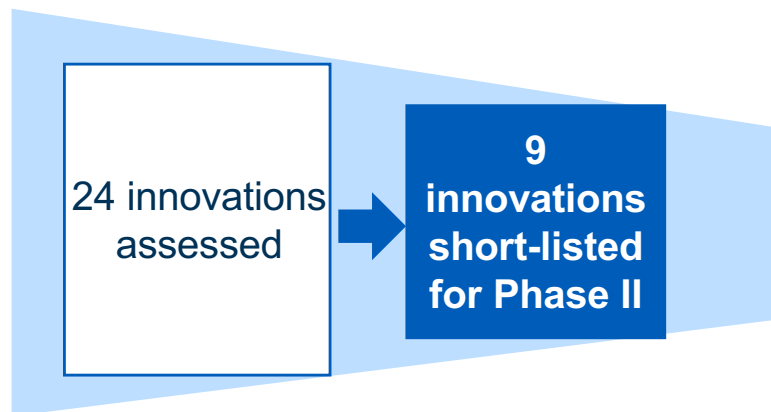
Inputs are used for weighting indicators to inform the prioritisation



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



9 innovations have been short-listed for Phase II based on...



- **Multiple public health benefits OR a strong unique benefit**
- **Broad antigen applicability**
- **And/ or additional strategic rationale for prioritisation**

9 innovations short-listed for further analysis under Phase II



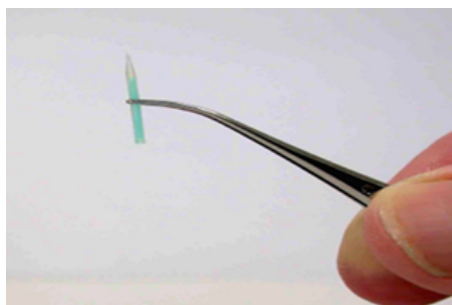
Microarray patches (MAPs)



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



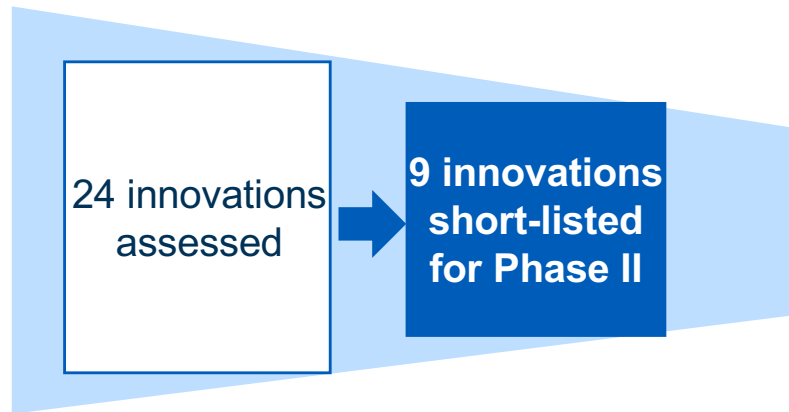
Combined Vaccine vial Monitor (VVM) and Threshold Indicator (TI)



Barcodes / Radio Frequency Identification (RFID)

Note: Innovation pictures are just examples of innovations

15 innovations have not been short-listed for Phase II ...



**15
innovations
not short-
listed for
Phase II**

- Other innovations offered similar benefits, plus additional benefits
- Potential public health benefits but some challenges
- Limited antigen applicability

VIPS aspirational vision



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**
- **Country studies**
- **Policy**
- **Procurement**
- **Implementation**
- **Etc.**

Catalyzing product development of vaccine technology innovations: Vaccine Innovation Prioritisation Strategy



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Menti survey



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- 1. Which of these 9 innovations are you familiar with?
(Check all that apply.)**



Mentimeter survey

part 1

About Microarray patches (MAPs)



- MAPs contain an array of micro-projections on a patch that deliver dry vaccine into the epidermis and/or dermis layers.
- Administered **without an applicator**, by applying pressure with fingers, or using **an integrated applicator**^a

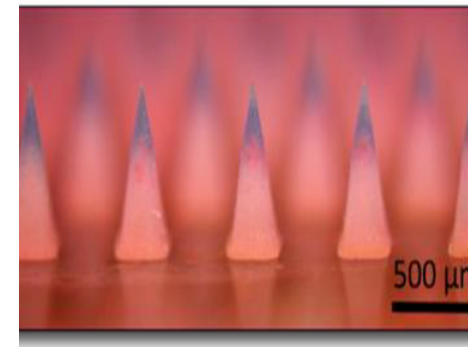
Vaxxas, 15 May 2019



micronbiomedical.com^b



WHO^c



Note: Innovation pictures are just examples of innovations



^a Lead candidate MAPs for vaccine delivery either have no applicator or an integrated applicator. Therefore, MAPs with a separate applicator are not considered in this assessment

^b <http://micronbiomedical.com/technology/> ; ^c https://www.who.int/immunization/research/meetings_workshops/PDVAC_2017_Delivery_Tech_Update_Zehring_PATH.pdf?ua=1

MAPs: Rationale for prioritisation



Potential to resolve reconstitution issues, multiple public health benefits, and broad applicability

MAPs have the potential to:

Health Impact

Coverage
and Equity impact

- Withstand heat and freeze exposure
- Positively impact coverage and equity:
 - Easier to use; use by lesser trained vaccinators or self-administration; alternative delivery scenarios
 - Less painful
 - Reduce stock-outs

Safety impact

- Reduced contamination/needlestick risk

Economic costs

- Save health care worker time

Potential breadth of innovation use

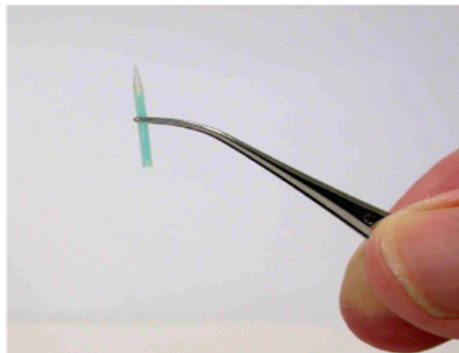
- Broad applicability and might facilitate novel vaccine combination
- Might also improve immunogenicity

About Solid-dose implants (SDIs)



- Vaccines reformulated into a **solid format, shaped like a needle** to be **implanted below the skin**.
- Dose either **dissolves immediately** or is **released slowly**.
- Contained in a **cartridge or cassette** for easy handling prior to administration.
- Administered with an **applicator to propel the SDI into the skin**, separate and re-usable, or integrated and single use.

Hirschberg HJHB, 2008 ^a



Separate, compressed gas-powered applicator (Bioneedle)

www.enesipharma.com ^b



Separate, spring-powered applicator (Implavax®)

Nemauro presentation ^c



Optional, separate applicator (Micropatch™)

Note: Innovation pictures are just examples of innovations

^a Hirschberg HJHB, van de Wijdeven GGP, Kelder AB, van den Dobbelsteen GPJM, Kersten GFA. Bioneedles as vaccine carriers. Vaccine. 2008 May 2;26(19):2389–97.

^b <https://www.enesipharma.com/technologies/platform/>; ^c Nemauro presentation. Teriparatide microneedle patch for osteoporosis, December 2018. Presented during telecon 12 February 2019.

SDIs: Rationale for prioritisation



Potential multiple public health benefits and broad applicability. Potential to solve issues associated with MAPs. e.g. reactogenicity, payload issues

SDIs have the potential to:

Health Impact

Coverage and Equity impact

- Withstand **heat and freeze exposure**
- Positively impact **coverage and equity**:
 - **Easier to use**: use by **lesser trained vaccinators**; **alternative delivery scenarios**
 - Increased **acceptability to standard** needle and syringe
 - Reduce **stock-outs**

Safety impact

- Reduced **contamination/needlestick risk**

Economic costs

- Save **health care worker time**

Potential breadth of innovation use

- **Broad applicability** to all parenteral vaccines and might facilitate novel vaccine combination

About Compact prefilled auto-disable devices (CPADs)



- Integrated primary containers and injection devices prefilled with liquid vaccines.
- Design prevents reuse and minimizes the space required for storage and shipping.

Three CPAD subtypes have been assessed:

- **Preformed CPADs:** Manufactured 'open', supplied sterile, ready to fill/seal by the vaccine manufacturer.
- **Blow-fill-seal (BFS) CPADs:** Manufactured using BFS automated technology; produced, filled, and sealed in a continuous process.
- **Other CPAD types.**



Preformed CPAD (Uniject™)



BFS CPAD (Apiject)



Other CPAD (Easyject)

Note: Innovation pictures are just examples of innovations

CPADs: Rationale for prioritisation



Potential multiple public health benefits, broad applicability and proven benefits in facilitating vaccine outreach

CPADs have the potential to:

Health Impact

Coverage and Equity impact

- Positively impact **coverage and equity**:
 - **Easier to use**: use by **lesser trained vaccinators**; **alternative delivery scenarios**
 - Increased **acceptability** of Uniject™ preformed CPADs
 - Reduce **stock-outs**

Safety impact

- Reduced **contamination/needlestick risk**

Economic costs

- Save **health care worker time**
- Reduce **storage and transportation costs**

Potential breadth of innovation use

- **Broad applicability** to all liquid, parenteral vaccines



About Dual-chamber delivery devices

- Dual chamber delivery devices are **fully integrated reconstitution technologies**.
- Prefilled with liquid and dry vaccine components, which are **mixed within the device and administered**.

www.pharmaceutical-networking.com^a



Dual chamber syringe
(Vetter Lyoject)

PharmaPan^b



Dual chamber blister with frangible
seal

Neopac^c



Dual chamber blister with frangible seal

Note: Innovation pictures are just examples of innovations

^a <https://www.pharmaceutical-networking.com/vetter-dual-chamber-delivery-systems/>

^b https://www.pharmapan.com/sites/default/files/downloads/2017-10/PHARMAPAN_Dual_Chamber_Blister_1.1.pdf

^c <https://www.webpackaging.com/en/portals/webpac/assets/11138717/neopacs-fleximed-now-in-large-format/>

Dual-chamber delivery devices: Rationale for prioritisation



Potential to resolve reconstitution issues, multiple public health benefits and broad applicability

Dual-chamber delivery devices have the potential to:

Health Impact

Coverage and Equity impact

- Positively impact **coverage and equity**:
 - **Easier to use**
 - Reduce **vaccine and diluent wastage and stock-outs** and simplify **inventory processes**
 - Increase **acceptability**: reduce the risk of reconstitution with the **wrong diluent**

Safety impact

- Reduced **contamination/needlestick risk**

Economic costs

- Save **health care worker time**

Potential breadth of innovation use

- **Broad applicability** to dry and other two-component vaccines.

About Autodisable (AD) sharps-injury protection (SIP) syringes



- **Single-use, disposable syringes** with a mechanism that covers the needle after use to **reduce the risk of accidental needlestick injury**.
- **Retraction of the needle** into the barrel after injection or a **needle shield**.
- Some syringes have **SIP features that are automatically activated** and others require extra activation steps by the end user.



A VanishPoint® retractable syringe
(Retractable Technologies, Inc.)



BD Eclipse™ syringe (BD, Franklin
Lakes, NJ) with needle shield

Note: Innovation pictures are just examples of innovations

AD SIP syringes: Rationale for prioritisation



Single public health benefit attributed to improved safety.

WHO Performance, Quality, and Safety group plans to require SIP features on both AD and reuse prevention syringes by the end of 2020.

AD SIP syringes have the potential to:

Safety impact

- Improve **safety** due to **reduced risk of contamination and needle-stick injuries/transmission** of bloodborne pathogens

Potential breadth of innovation use

- **Broad applicability** as AD SIP syringes can be applied to all parenteral vaccines

About Freeze damage resistant liquid formulations



- **For many vaccines, when frozen** the antigen-adjuvant particles agglomerate and sediment - resulting in the **irreversible loss of potency.**
- **Developing novel freeze-stable formulations** using different excipients (stabilising agents) **could prevent agglomeration and stabilise the potency of vaccines.**
- The addition of excipients has been **demonstrated to reduce the freeze-sensitivity of hepatitis B vaccine** and other vaccines containing aluminum-salt adjuvants including **diphtheria, tetanus and pertussis (DTP); and pentavalent** (hepatitis B, DTP, Haemophilus influenza type b) **vaccines.**



Note: Innovation pictures are just examples of innovations

^a <https://www.myelomacrowd.org/wp-content/uploads/2015/05/vials.jpg>

^b <https://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/Infection-Prevention-and-Control-for-Clinical-Office-Practice-Multidose-Vials.aspx>

Freeze damage resistant liquid formulations: Rationale for prioritisation



Safeguards vaccine potency and prevents vaccine wastage.

Prioritisation could raise the visibility of the technology to vaccine manufacturers currently developing liquid vaccines with aluminum adjuvants.

Freeze damage resistant liquid formulations have the potential to:

Health Impact

- Improve **freeze resistance of liquid formulations**
 - **Safeguard the potency of the vaccine if accidentally exposed to freezing temperatures** and help to **prevent vaccine wastage**

Potential breadth of innovation use

- **Broad applicability to all liquid vaccines** containing aluminum-salt adjuvant and potentially to **other freeze-sensitive vaccines**

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



- Liquid vaccine formulations that are **sufficiently heat stable to be kept in a CTC**.
- CTC use of vaccines allows for **single excursion of the vaccine into ambient temperatures** not exceeding +40°C for a minimum of 3 days, just prior to administration.
- Heat-stable vaccines differ in the **length of time** they can be stored in a CTC and the **maximum temperature** they can endure while **remaining stable and potent**.
- CTC qualification involves regulatory approval and prequalification by WHO.



Note: Innovation pictures are just examples of innovations

Heat stable/CTC qualified liquid formulations: Rationale for prioritisation



Potential multiple public health benefits and WHO recommended

Heat stable/CTC qualified liquid formulations have the potential to:

Health Impact

Coverage and Equity impact

- Improve **vaccine effectiveness**: less susceptible to heat damage
- Reduce **likelihood of freeze exposure**
- Positively impact **coverage and equity**:
 - **Easier to use** ; alternative delivery scenarios; ease cold chain logistics for health care workers
 - Increase **acceptability**
 - Reduce **stock-outs**

Safety impact

- Reduced **contamination/needlestick risk**

Economic costs

- Reduce **storage and transportation volume and associated costs**
- Save **health care worker time**

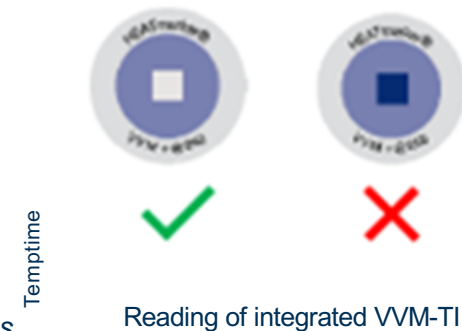
Potential breadth of innovation use

- **Broad applicability** to all vaccines that are currently liquid and thermostable

About Combined Vaccine Vial Monitor (VVM) and Threshold Indicators (TI)



- Combined VVM-TIs on primary containers **undergo gradual colour change** up to a specified peak threshold temperature and **rapidly react if exposed at or above the threshold temperature**.
- Currently, **VVMs and TIs are not integrated**:
 - **VVMs on primary containers** and **standalone TIs** are currently used when vaccines are kept in a controlled temperature chain (CTC)
 - TIs **purchased and distributed separately** from the vaccine and kept at temperatures below their threshold
 - VVM response **not rapid enough at higher temperatures** (e.g. $>37^{\circ}\text{C}$ or 40°C), whereas TI reacts rapidly if exposed at or above a defined threshold temperature.
- There are two types of combined VVM-TIs:
 - **VVM and TI placed together and reviewed separately**
 - **TI is integrated into the VVM**: looks and is interpreted identically to the existing VVMs.



Note: Innovation pictures are just examples of innovations

Combined VVM and TIs: Rationale for prioritisation



Potential to improve upon the current use of VVMs with separate TI indicators.
Potential to facilitate use of vaccines in a CTC.

Combined VVM and TIs have the potential to:

Health Impact

Coverage
and Equity impact

- Positively impact **coverage and equity**:
 - **Easier to use**
 - Provide **more accurate assessment of the heat exposure status** of a vaccine, particularly when used in the CTC
 - Reduce **TI stock-outs**

Economic costs

- Save **health care worker time**

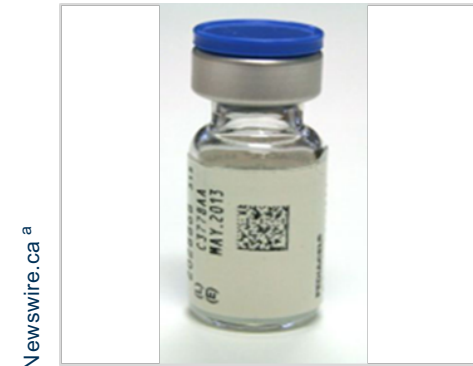
Potential breadth of innovation use

- **Broad applicability** to all vaccines, even if likely to be **most useful for vaccines prequalified for use in a CTC**

About Barcodes



- **Encode information** such as **product numbers, serial numbers, supplier data, batch numbers and expiry dates.**
- **Scanned electronically** using two dimensional (2D) scanners, laser or mobile device cameras to automatically capture information.
- Enable **tracking and monitoring of vaccine products** in supply chains.
- Possibility to **automatically import data into patient electronic medical records (EMRs).**
- VIPS assessment based on **barcode placement on vaccine primary and higher packaging levels.**



Barcode on primary packaging



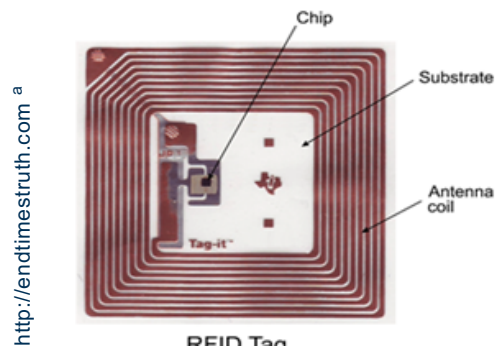
Barcode on secondary packaging

Note: Innovation pictures are just examples of innovations

About Radio Frequency Identification (RFID)



- RFID tags can be **affixed to vaccine primary containers**.
- **Store a wide range of information** useful for **inventory control**, **patient monitoring** and **providing data for electronic medical record systems**.
- An RFID system consists of **three components**; (i) a tag, (ii) a reader and (iii) **the middleware**.
- Possibility to **identify tags within range** – no need to individually scan every tag.



RFID Tag

RFID Tag



RFID tags used for hospital medication trays



Handheld RFID readers & scanners

Note: Innovation pictures are just examples of innovations



^a <http://endtimetruth.com/wp-content/uploads/2014/01/RFID-chip-and-antenna-3.png>

^b <http://www1.prweb.com/prfiles/2014/10/05/12223944/HCL%20-%20Seal%20Tags%20Kit%20Check.jpg>

^c <https://www.abr.com/products/rfid-products/>

Barcodes and RFIDs: Rationale for prioritisation



Potential to improve coverage and increase measurement of coverage and safety monitoring. WHO recommendations and UNICEF interest.

Barcodes and RFIDs have the potential to:

Health Impact

Coverage and Equity impact

- Positively impact **coverage and equity**:
 - Reduce **missed opportunities**; increase **acceptability** by **improving patient safety**
 - Reduce **stock-outs**: improve **traceability** ; increase **efficiencies in stock management**

Economic costs

- Save **health care worker time**

Potential breadth of innovation use

- Barcodes and RFIDs could be **applied to all vaccines**, there are no restrictions based on technical feasibility.

Menti survey



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2. Which innovations are of most interest to your organization ?

Mentimeter survey

part 2

Catalyzing product development of vaccine technology innovations: Vaccine Innovation Prioritisation Strategy



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Under Phase II the 9 short-listed innovations will be further analysed for final prioritisation of 3-4 innovations

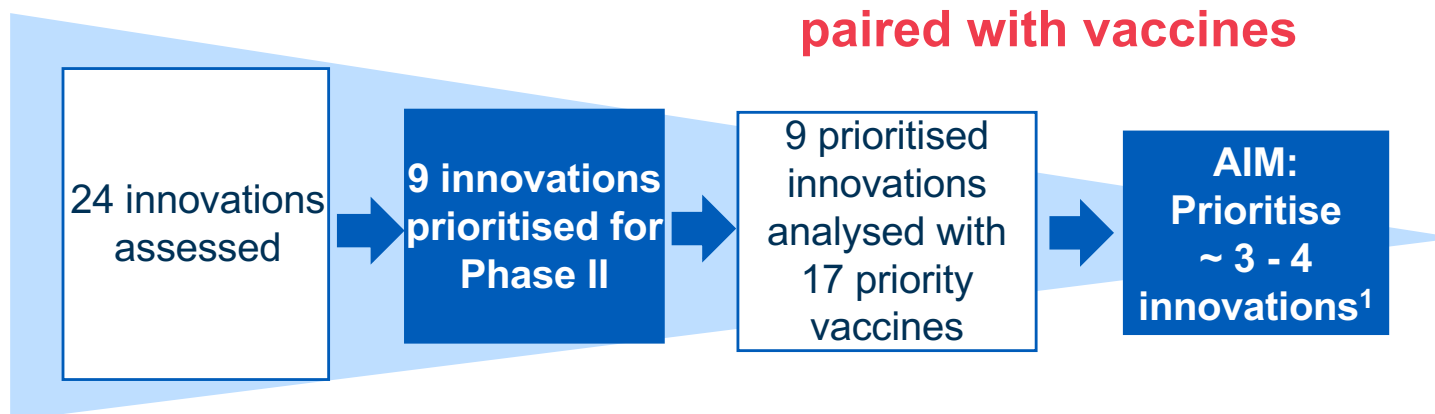


December 2018 – June 2019

July 2019 – March 2020

Phase I: Initial prioritisation of innovations

Phase II: Final prioritisation of innovations paired with vaccines



Short-listed innovations will be further analysed with 17 priority vaccines



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.

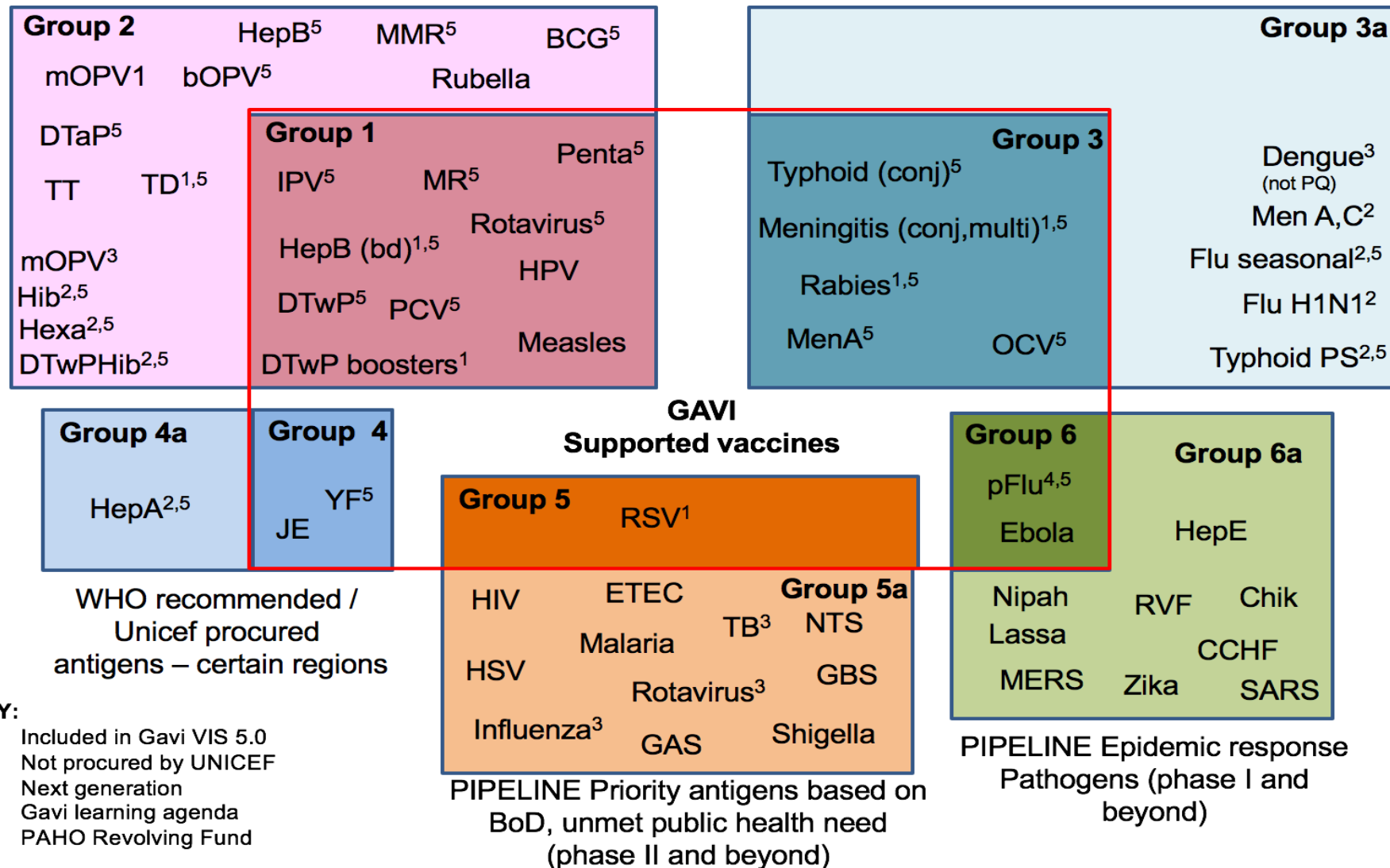
Landscape of vaccines in VIPS scope



Vaccine antigens and categorisation

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

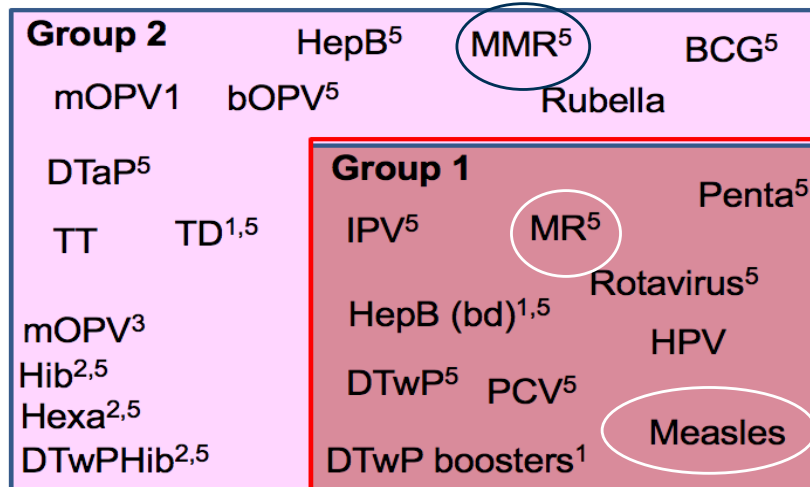
WHO recommended / Unicef procured
antigens – high risk pops



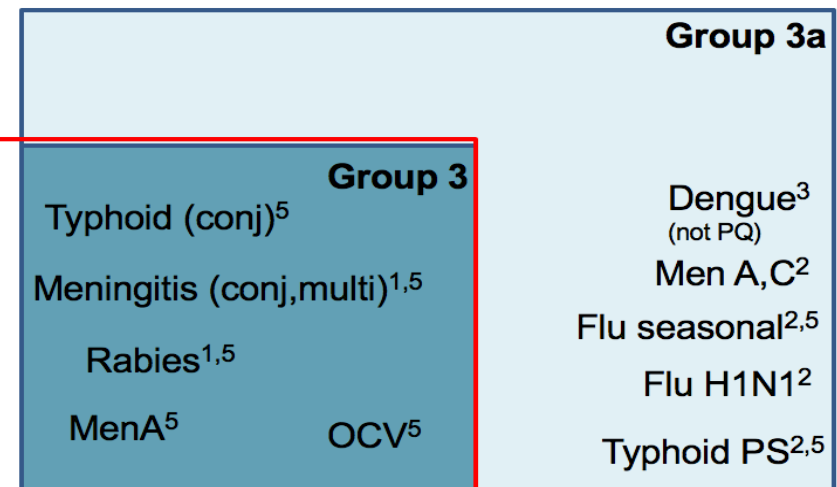
Landscape snapshot of antigen categorisation to map overlap

Vaccine antigens and categorisation

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

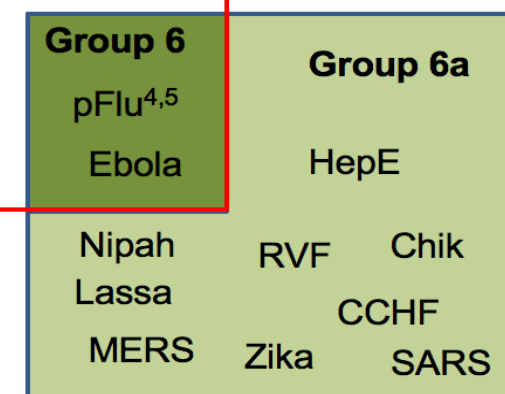
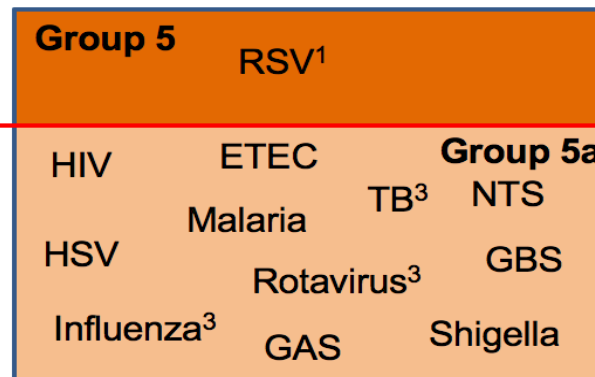
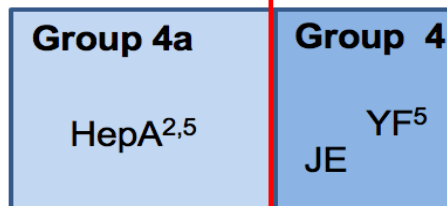


WHO recommended / Unicef procured antigens – high risk pops



GAVI

Supported vaccines



WHO recommended / Unicef procured antigens – certain regions

KEY:

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

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

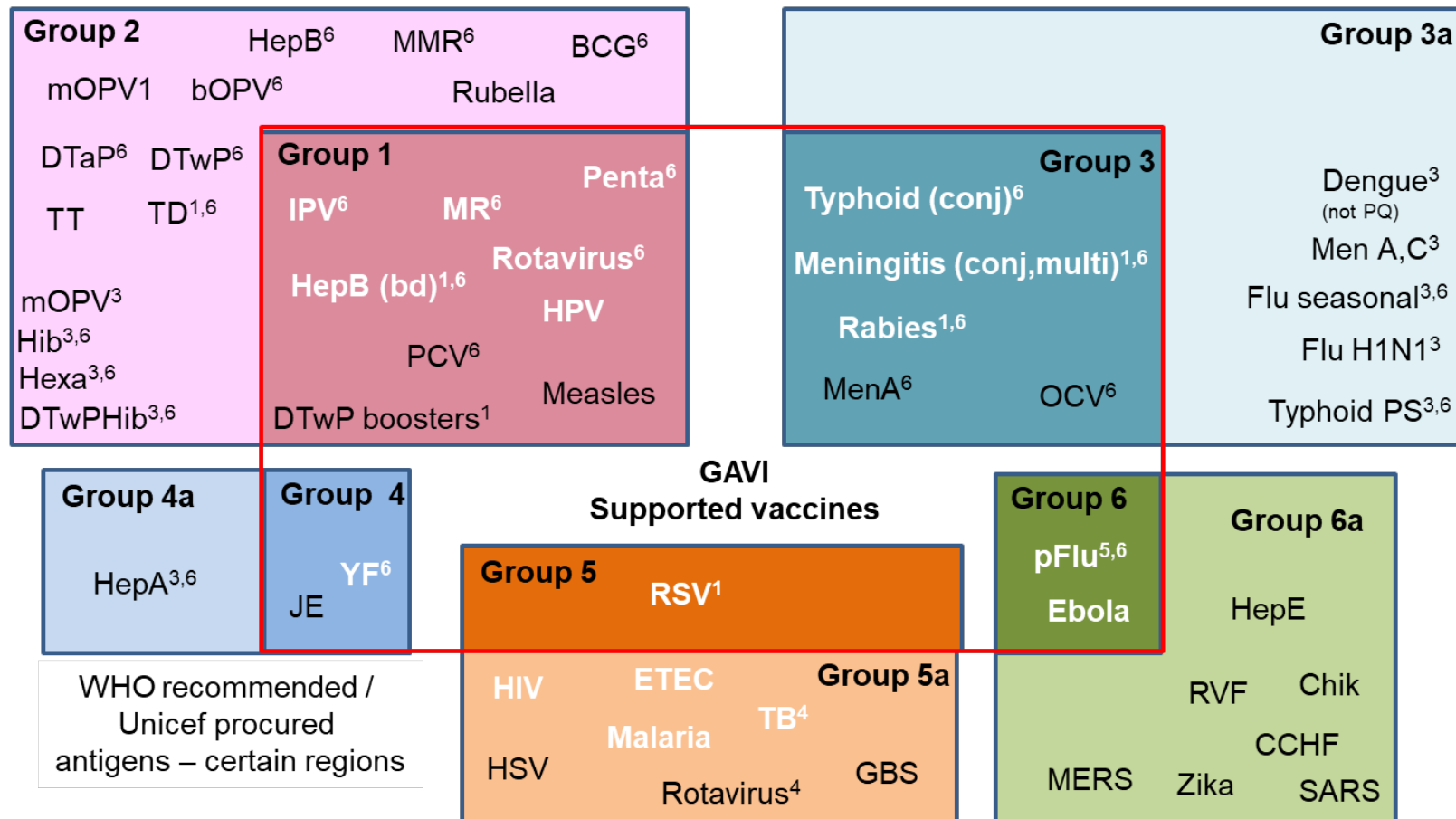
PIPELINE Epidemic response Pathogens (phase I and beyond)

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)

Evaluation framework for Phase II (1/2)



	Criteria	Indicators
Primary ranking criteria	Health Impact	<ul style="list-style-type: none"> Vaccine efficacy Vaccine effectiveness Ability of the innovation to withstand heat exposure¹ Ability of the innovation to withstand freeze exposure¹
	Coverage and equity impact	<ul style="list-style-type: none"> Number of fully or partially immunised individuals (relative to target pop) Ease of use² Presentation which helps prevent missed opportunities due to reluctance to open MDV without preservative
	Safety impact	<ul style="list-style-type: none"> Number of vaccine product-related adverse events Likelihood of contamination²
	Economic costs (i.e. Commodity, Delivery and Introduction and recurrent costs)	<ul style="list-style-type: none"> Total cost of a vaccine regimen with the innovation, including wastage Total cost of delivery technology(ies) used for the vaccine regimen, including wastage Total cost of safety boxes used for the vaccine regimen, incl wastage Total cost of storage and transport of commodities (per vaccine regimen)¹ Total cost of the time spent by staff (per vaccine regimen)¹ Total cost of introduction and recurrent costs (not otherwise accounted for)¹

¹ Same indicators as for Phase I but further assessed under Phase II due to the antigen/vaccine pairing

² This indicator is re-assessed in Phase II only when the comparator for a specific vaccine is a MDV, requiring a new evaluation – The comparator SDV is assessed in Phase I

Evaluation framework for Phase II (2/2)



Criteria

Indicators

Secondary ranking criteria¹

Technology readiness

- **Clinical development** pathway complexity
- **Technology development** challenges
- **Regulatory** pathway complexity
- Complexity of **manufacturing** the innovation
- Robustness of the innovation **pipeline**

Commercial feasibility

- Potential breadth of **market size**
- Existence of **partnerships** to support development and commercialisation
- Known **barriers to global access** to the innovation
- **Stakeholders' interest**

¹ These criteria will be evaluated in an absolute manner, not relative to a comparator.

In Phase II, VIPs is engaging with the Delivery Technologies Working Group (DT-WG)



DT-WG goals and objectives

- Platform for **industry and the public sector** to engage on the presentation, packaging, and delivery aspect of vaccine products.
- Inform industry about **LMIC programmatic preferences & operational realities**.
- Optimise innovation of immunisation products for public-sector use.
- Sensitize the public sector to **industry constraints and economic realities** of investing in product development.

Consultations objectives

- Update broader set of immunisation stakeholders, **including industry**, on VIPs.
- Obtain **feedback on VIPs prioritised innovations** from the perspective of **technical feasibility, manufacturability, regulatory hurdles**.

A final report will be published by Q3/Q4 2020



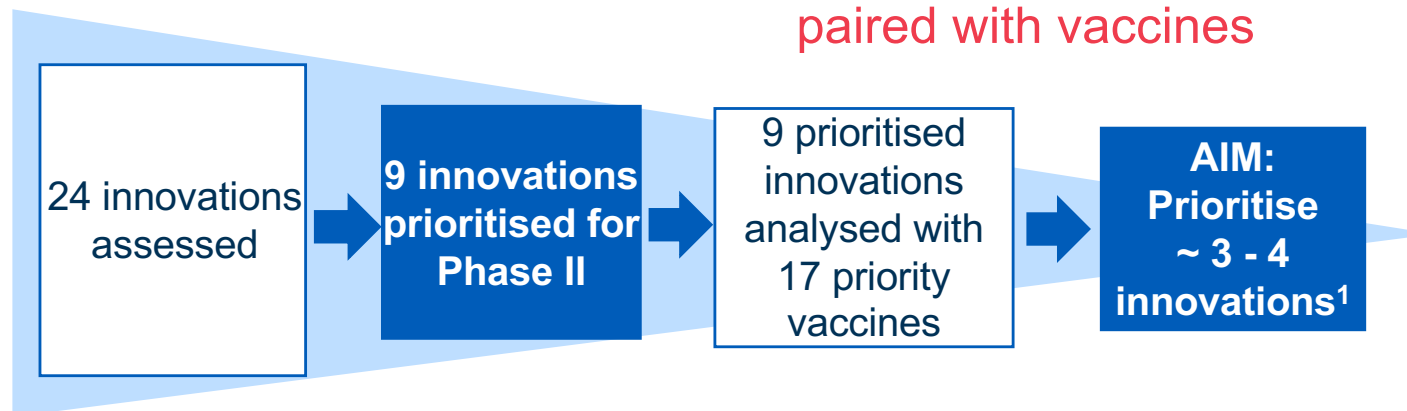
December 2018 – June 2019

July 2019 – March 2020

April-December 2020

Phase I: Initial prioritisation of innovations

Phase II: Final prioritisation of innovations paired with vaccines



Publication of a **final report**:

- Process and methodology;
- **Most valuable innovations** including 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.

Catalyzing product development of vaccine technology innovations: Vaccine Innovation Prioritisation Strategy



Agenda

<i>Topic</i>	<i>Presenter</i>
• The Alliance VIPS initiative	Marion Menozzi, Gavi
• Nine prioritised innovations from the VIPS initial prioritisation phase	Debra Kristensen, PATH
• Process for the final prioritisation phase	Birgitte Giersing, WHO
▶ Q&A	Dr. Sotiris Missailidis
• Panel discussion - 'How VIPS may help drive vaccine delivery innovations but what else is needed beyond the prioritisation and communication?'	Dominic Hein, Gavi
• Q&A	Dr. Sotiris Missailidis