



The Vaccine Innovation Prioritisation Strategy (VIPS): driving innovations to improve vaccine delivery in low- and middle-income countries

GVIRF

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Jean-Pierre Amorij (UNICEF) on behalf of VIPS



Agenda



- **VIPS and vaccine innovations**
- Heat- stable and Controlled Temperature Chain qualified vaccines update
- Micro-array patches update
- Barcodes



VIPS partners work closely to accelerate three priority innovations to contribute to coverage and equity goals



Microarray patches



Heat-stable and CTC qualified vaccines



Barcodes



The VIPS Alliance has developed and is implementing **end-to-end roadmaps**¹, **aligned amongst partners**, **including 5-year action plans**, to accelerate development and uptake of each of the three VIPS prioritised innovation in LMICs.

¹ Roadmap for MAPs has been published: https://www.gavi.org/sites/default/files/about/market-shaping/VIPS-Alliance-Action-Plan-for-MAPS_Public-Summary.pdf; roadmaps for heat stable and CTC qualified vaccines and barcodes are still under development.

... and to monitor the innovation space



We continue to actively **monitor the vaccine product landscape for new innovations and new data on existing technologies**. If compelling data is identified, VIPS could expand the priority list; however, so far **VIPS remains focused on accelerating development and impact of the original three prioritised innovations**.

Primary containers



Delivery devices



Integrated containers and delivery devices



Formulations



Packaging



Labelling



Agenda



- VIPS and vaccine innovations
- **Heat- stable and Controlled Temperature Chain (CTC) qualified vaccines**
- Micro-array patches update
- Barcodes



Thermostability remains a key concern for LMICs, for both EPI programs as well as pandemic response



Thermostability remains a key immunisation barrier for licensed vaccines...

... as well as for pandemic response

Ranked top 3 for Penta, Hep B birthdose, IPV, HPV, Rota, Yellow Fever	Vaccine ineffectiveness/wastage due to heat exposure	Ranked top 3 for Penta, MR, Men A, Hep B birthdose, IPV, Rabies, Rota, TCV
	Vaccine ineffectiveness/wastage due to freeze exposure	
	Cold chain requirements during outreach	Ranked top 3 for MenA, HepB birthdose, IPV, HPV, Rota
	Vaccine wastage or missed opportunities due to multi-dose vial	
	Reconstitution related safety issues	
	Reduced acceptability due to painful administration	
	Difficult preparation requiring trained personnel	
	Difficult to deliver vaccine to correct injection depth	

Source: VIPS country consultation 2020

Play (k) But in several respects, these vaccines are not perfect. gates notes

“a perfect vaccine would be made so that it can be transported at normal temperatures, without refrigeration”

Source: GatesNotes; “Here’s what a perfect vaccine would look like”

We need more heat-stable and CTC qualified vaccines in LMICs, especially as the thermostability benefits of vaccines increase with the number of improved thermostable vaccines available in countries.



VIPS has prioritised CTC qualified and heat-stable vaccines



CTC qualified vaccines



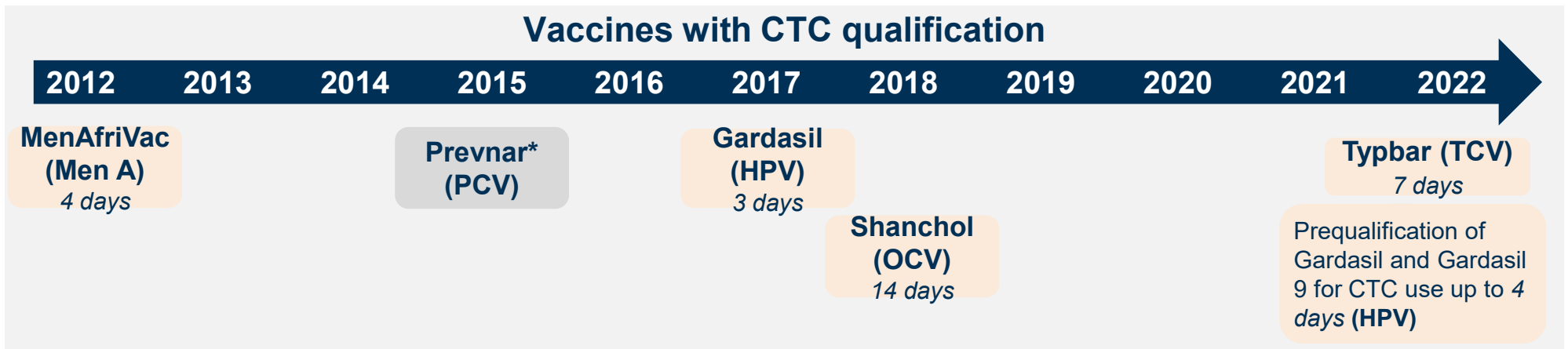
- **DEFINITION:** A specific set of conditions allowing for a vaccine to be stored and transported **outside of the traditional 2° to 8°C cold chain.**
 - 1) One excursion, just prior to administration
 - 2) Specifically limited duration (**at least 3 days**)
 - 3) Ambient temperatures **up to 40°C+**
 - 4) Full validation = ✓ Tested (for safety & stability) ✓ Licensed ✓ Prequalified
- **KEY TOOLS = VVM + Peak Threshold Temperature Indicator**
- **PRIORITIES:**
 - Vaccines delivered through **campaigns or special strategies**
 - **Vaccines that can achieve the CTC qualification without reformulation**

Heat-stable vaccines



- Refers to **improvement in long-term storage** of vaccines, including shelf-life, e.g., to the following stability targets:
 - a. From ultra cold-chain to -20C
 - b. From -20C to 2-8C
 - c. From VVM7 or VVM14 to VVM30
- **In order to achieve these improvements, reformulation may be needed, and/or other novel / complex thermostabilisation methods.**

4 CTC qualified products are on the market, including recent approval for TCV but some challenges in uptake



- CTC uptake in country has been limited to date.
- Over the last years, we have learnt that programmatic benefits are context and vaccine-specific, with limited evidence available, and the environment is evolving (e.g., CCE investments with COVID-19 pandemic and some trends towards integrated campaigns).
- However, CTC remains a compelling tool for last mile outreach.



*Pfizer's Prevnar 13® pneumococcal conjugate vaccine was approved in 2015 for use at temperatures up to 40°C for three days. However, this indication was removed in 2016

Ongoing CTC activities and plans to expand the evidence base and support extended implementation



WHO activities on CTC

1 Support country implementation



- **CTC implementation app**
- **Guidelines & advocacy**
- **Training materials**

2 Increase number of CTC qualified products



- **WHO PQ support**
- **Manufacturer engagement & support**

VIPS plans

3 Generate evidence on CTC impact incl most valuable use cases and settings



- Explore opportunities to conduct **country pilots / implementation research for priority vaccines**



VIPS has currently identified 8 priority vaccines for CTC pending additional consultations



PRIORITY VACCINE LIST for CTC in alphabetical order

dT (reduced d antigen for adults/adolescents)
Hepatitis B (birth dose)
Human papillomavirus (HPV)
Measles-Rubella (MR) - MAP ¹
Meningitis A,C, W, Y (X)
Oral Cholera Vaccines (OCV)
SARS-COV-2
Typhoid conjugate vaccine (TCV)

- Based on a transparent framework and expert consultations, a priority list of 8 vaccines has been identified and recently **validated via country and public consultations.**
- **Evidence on programmatic impact for available priority vaccines** should be generated through implementation research and/or country pilots.

¹ MR-MAP is included here due to the stage of development and the thermostability data available, but all other vaccines prioritised under the vaccine MAPs prioritisation exercise would be targets for CTC



Agenda



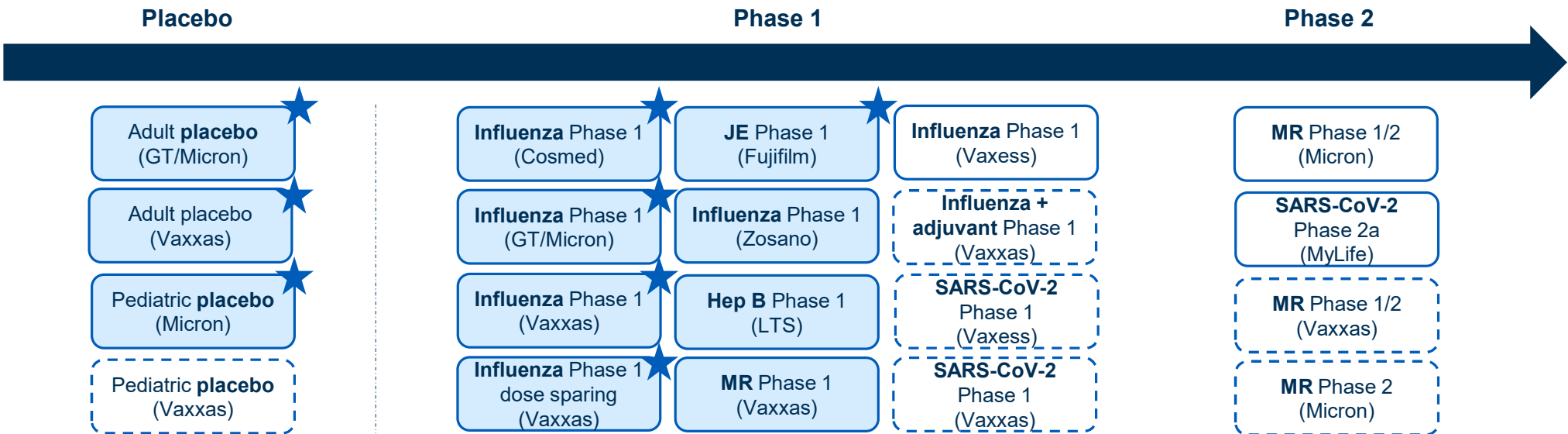
- VIPS and vaccine innovations
- Heat- stable and Controlled Temperature Chain qualified vaccines
- **Micro-array patches**
- Barcodes



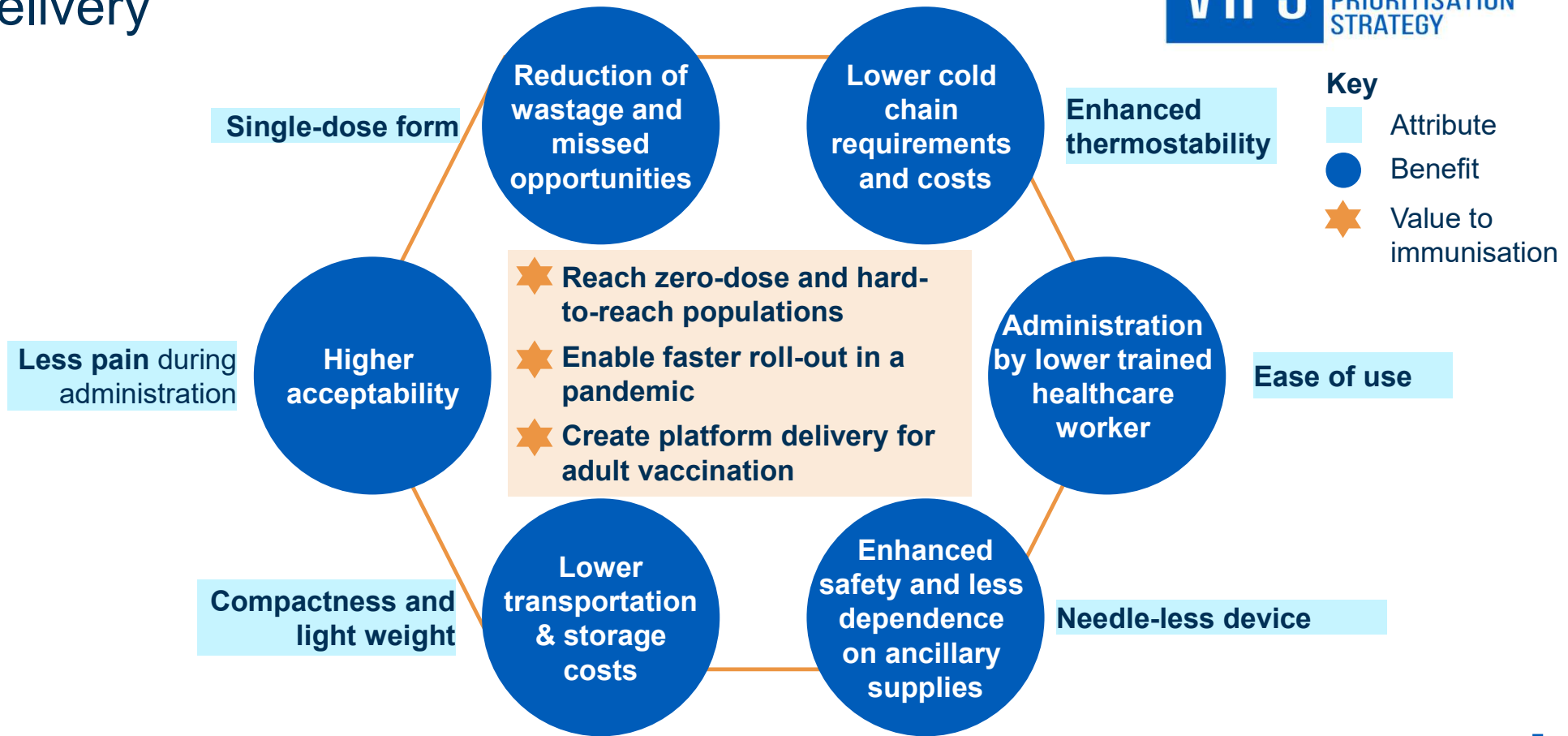
The clinical evidence base for vaccine-MAPs is expanding



Results are published or anticipated for MR, Influenza, SARS-CoV-2, Hep B and JE in Phase 1, as well as Phase 2 studies for MR and SARS-CoV-2



Vaccine-MAPs could transform immunisation delivery



Across immunisation programmes, vaccine-MAPs can bring greater impact through increased equitable coverage and access



MR

Increase equitable coverage and contribute to MR elimination especially for HTR populations, due to (i) **enhanced thermostability** (ii) **application by lower-skilled individuals**, and (iii) **reduction of missed opportunities to vaccinate**



HPV

Increase access while reducing costs due to (i) **potential to train teachers to apply MAP** and to deliver to schools with other programs given **ease-of use** and (ii) the **potential for cheaper storage and distribution in outreach settings**



Pandemic preparedness and response

Enable broader access to and faster¹ rollout of vaccines in a pandemic due to (i) **enhanced thermostability**, (ii) **application by lower-skilled individuals**, and (iii) **less dependency on antigen and ancillary supply in the event of shortages**



1. Assumes "final" MAP will be a platform technology, requiring similar development time to N&S

VIPS has identified 12 priority vaccine targets for vaccine-MAPs



PRIORITY VACCINE LIST for vaccine-MAPs in alphabetical order

PRIORITY VACCINE LIST for vaccine-MAPs in alphabetical order	
Priority 1	Hepatitis B virus
	Measles, rubella (MR)/ Measles, mumps and rubella (MMR) viruses
	Human papillomavirus
	Rabies virus
	Yellow Fever
	Influenza virus, seasonal and pandemic
	SARS-CoV-2
Priority 2	Group B streptococcus (GBS), S agalactiae
	Neisseria meningitidis A,C,W,Y,(X)
	Salmonella Typhi
	Streptococcus pneumoniae

▪ Based on a transparent framework and expert consultations, a priority list of vaccines has been identified and **validated¹ via country and public consultations.**

¹ The list will be also discussed in an upcoming meeting of the Product Development Advisory Committee (PDVAC) of WHO in Q2 2023



The VIPS Alliance is working to address the main challenges to accelerate vaccine-MAPs



Demand uncertainty



High upfront costs



Technical and regulatory risks



Priority vaccines



Risk-sharing approaches for R&D and manufacturing



Regulatory pathways



Global health impact



COGS assessment and impact of **scale**



Demand sizing



Market incentives



Country engagement



Agenda



- General
- Heat- stable and Controlled Temperature Chain qualified vaccines
- Micro-array patches
- **Barcodes**



In 2020 VIPS prioritised barcodes on vaccine products based on broad public health benefits



Barcodes



2D barcode on primary container



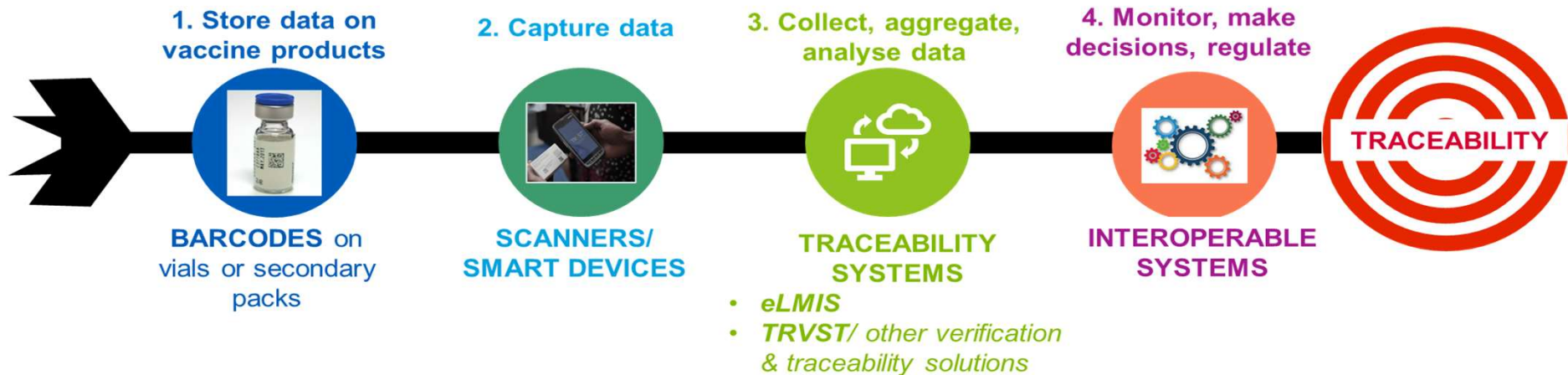
Barcode on secondary packaging

Challenges or use cases that may be solved or supported by implementing barcodes:

- **Traceability** of vaccines in the supply chain including stock management
- **Visibility** of stock at certain nodes in the supply chain, through automation of stock management improving data quality (time and accuracy) and vaccine forecasting
- Reduce risk of **falsified vaccines and diversion**
- Facilitating product **recalls**
- Facilitate reporting and assessment of **AEFI** when linked to individual patient record
- Improving efficiency & accuracy of **immunization record keeping**

However, barcodes do not work alone and are one piece of the puzzle

To ensure full traceability multiple other systems and processes are needed



ENABLING ENVIRONMENT

Governance, available and skilled workforce, IT equipment and internet, standards, policy, sustainable financing

VIPS activities on barcodes



2022

1 PHASE 1: IDENTIFICATION OF USE CASES FOR BARCODES



- **Benefit assessment** of barcodes on secondary and primary packaging
- **Specification needs** for each use case to inform labelling guidelines

Q1'2023

2 PHASE 2: IMPLEMENTATION FEASIBILITY & ROADMAP FOR BARCODES



- Assessment of **implementation feasibility, country readiness and high-level costs**
- **Roadmap** including action plan to advance barcodes **building on synergies** with existing traceability initiatives

TBD (~2023/24)

3 BARCODES PILOT(S)



- **Demonstrate barcodes impact** in countries to incentivize further countries and donors' investment
- Inform barcoding **implementation plan** by identifying lessons learnt and best practices

Current ongoing



Thank you!



Q & A

Contact information for post GVIRF questions or feedback

Please contact VIPS leads:

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- Birgitte Giersing, WHO: giersingb@who.int
- Jean-Pierre Amorij, UNICEF: jamorij@unicef.org

Additional VIPS publications present country needs and lessons learnt for vaccine innovation in LMICs



1 VIPS prioritisation process & outcomes



Commentary
 A global collaboration to advance vaccine product innovations – The Vaccine Innovation Prioritisation Strategy
 Debra Kristensen^{a,*}, Birgitte Giersing^b, Julian Hickling^c, Fatima Kazi^d, Tiziana Scarna^e, Anna-Lea Kahn^b, Viviana

2 Country insights gathered during VIPS



Vaccine innovation prioritisation strategy: Findings from three country-stakeholder consultations on vaccine product innovations

Mercy Mvundura^{a,*}, Collrane Frivold^a, Anna Janik Osborne^b, Priyanka Soni^b, Joanie Robertson^a, Sandeep Kumar^c, Jacqueline Anena^d, Abdoulaye Gueye^e, Marion Menozzi-Arnaud^b, Birgitte Giersing^f, Anna-Lea Kahn^f, Tiziana Scarna^b, Debra Kristensen^a

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^f Vaccine Product & Delivery Research, Immunisation, Vaccines and Biologicals, World Health Organization, CH-1211 Geneva 27, Switzerland

3 Lessons learnt & 'Innovation Conundrum'



Review
 Strategies for vaccine-product innovation: Creating an enabling environment for product development to uptake in low- and middle-income countries

Birgitte Giersing^{a,*}, Natasha Shah^a, Debra Kristensen^b, Jean-Pierre Amorij^c, Anna-Lea Kahn^a, Kristoffer Gandrup-Marino^c, Courtney Jarrahan^b, Darin Zehrung^b, Marion Menozzi-Arnaud^d

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1 <https://doi.org/10.1016/j.vaccine.2021.05.102>

2 <https://doi.org/10.1016/j.vaccine.2021.08.024>

3 <https://doi.org/10.1016/j.vaccine.2021.07.091>



The VIPS Webpage

A screenshot of the VIPS webpage. At the top left is the Gavi logo. A navigation bar contains links for 'OUR ALLIANCE', 'PROGRAMMES & IMPACT', 'INVESTING IN GAVI', '#VACCINESWORK', and 'NEWS & RESOURCES'. Below the navigation bar is a breadcrumb trail: 'Home > Our Alliance > Market Shaping > The Vaccine Innovation Prioritisation Strategy'. A large image shows a healthcare worker in an orange uniform drawing vaccine into a syringe while a woman holds a baby. A white callout box on the left contains the text 'The Vaccine Innovation Prioritisation Strategy (VIPS)'. Below the image is a paragraph of text and a small VIPS logo.

<https://www.gavi.org/our-alliance/market-shaping/vaccine-innovation-prioritisation-strategy>

VIPS ALLIANCE 2021-2025 ACTION PLAN FOR MICRO-ARRAY PATCHES

The VIPS Alliance's long-term vision for vaccine micro-array patches (MAPs) is to implement MAP products for priority vaccines to overcome immunisation barriers to ensure equitable access to, and improved effectiveness of, vaccines in LMICs and contribute to global health security. To achieve this long-term vision, the VIPS Alliance has developed an end-to-end five-year Action Plan for vaccine MAPs that:

- Identifies activities needed to accelerate development and future uptake of vaccine MAP products for LMIC use.
- Has the aspiration to advocate for vaccine MAPs in general and attract the interest of other global health partners and funders.

More details on the five measurable target outcomes and underlying activities that have been identified can be found in the Public Summary of the VIPS Alliance Action Plan for MAPs (link below). The public summary is a condensed version including key background on MAPs and the list of target outcomes and activities. A longer version of the Action Plan is available upon request.

- Download: [VIPS Alliance Action Plan for MAPS – Public Summary](#)

https://www.gavi.org/sites/default/files/about/market-shaping/VIPS-Alliance-Action-Plan-for-MAPS_Public-Summary.pdf