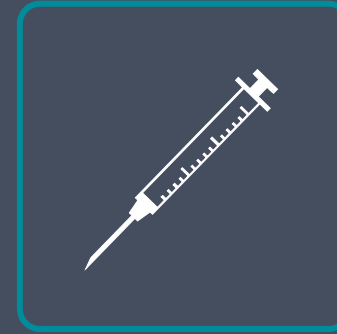


September 12, 2026

Accelerating Vaccine Access Through Innovation

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(she/her)



Background

Vaccine innovation case studies

Conclusions

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Trends in the market



- In LMIC markets, vaccines are typically stored in a **multidose glass vial** and administered using an **autodisable needle & syringe (AD N&S)**.
- In HIC markets, there has been a general shift away from traditional vial and ampoule presentations to **prefilled syringes**.
- Prefilled syringes are now also routinely used for **immunization** in HICs.
- In addition to prefilled syringes, other vaccine product innovations have been developed to address barriers to vaccine uptake in LMICs.

Vaccination barriers

Barriers to achieving vaccine coverage goals are multifaceted and differ by vaccine, delivery scenario, population, and geography:

Supply chain &
logistics constraints

Physical access &
geographic inequities

Health system &
service delivery
barriers

Human resource
constraints

Political & governance
challenges

Conflict, fragility, &
displacement

Data & identification
gaps

Vaccine hesitancy &
low demand



Innovative delivery strategies
are needed to eliminate
health inequities

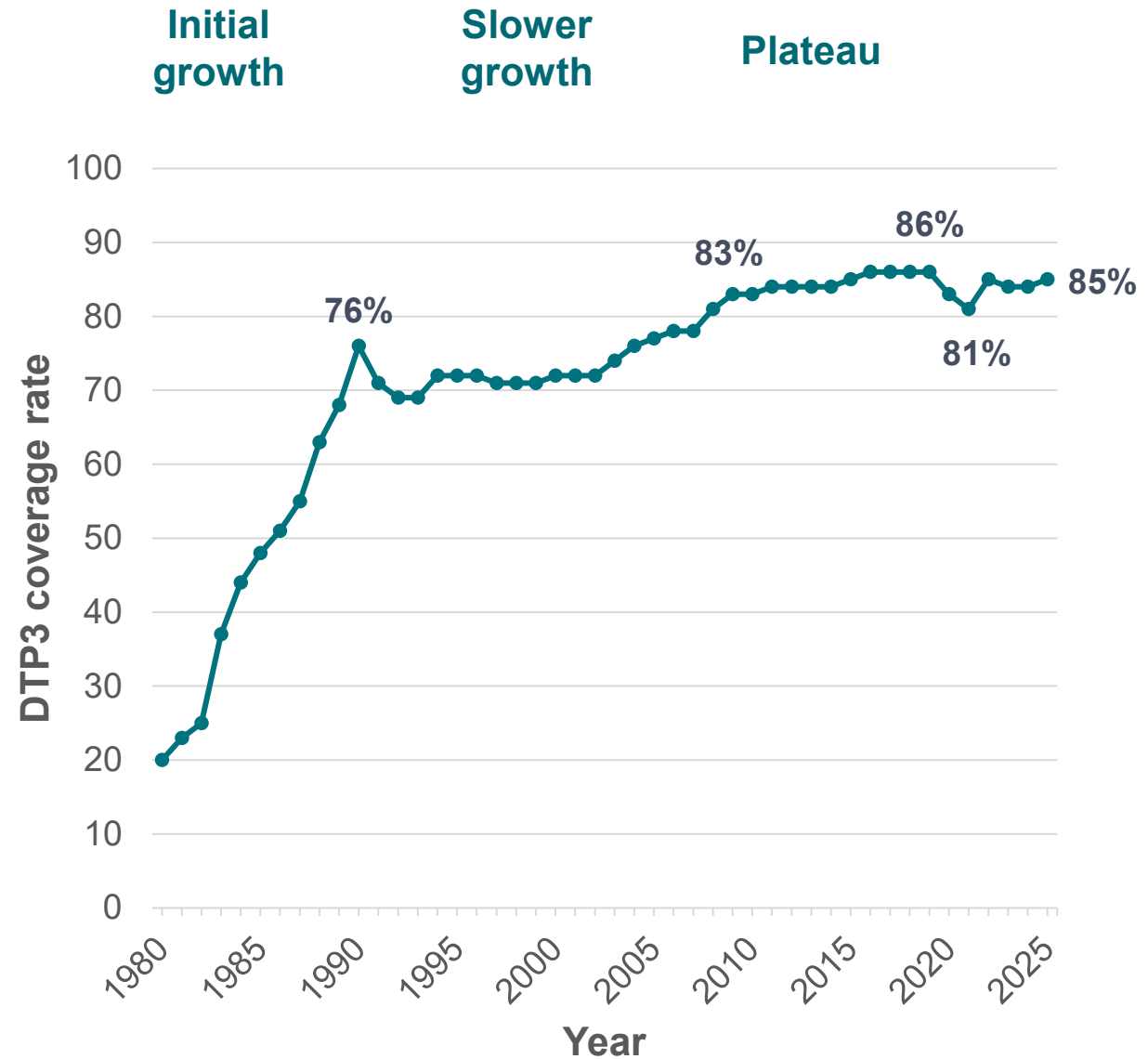
Global health need: Vaccines that can travel to the people who need them

Progress on global vaccine coverage significantly stalled during the pandemic.

In 2025, there were 13.5 million zero-dose children, primarily in the most disadvantaged communities.

New tools, such as vaccine innovations, can fill the gap **if they have the right attributes.**

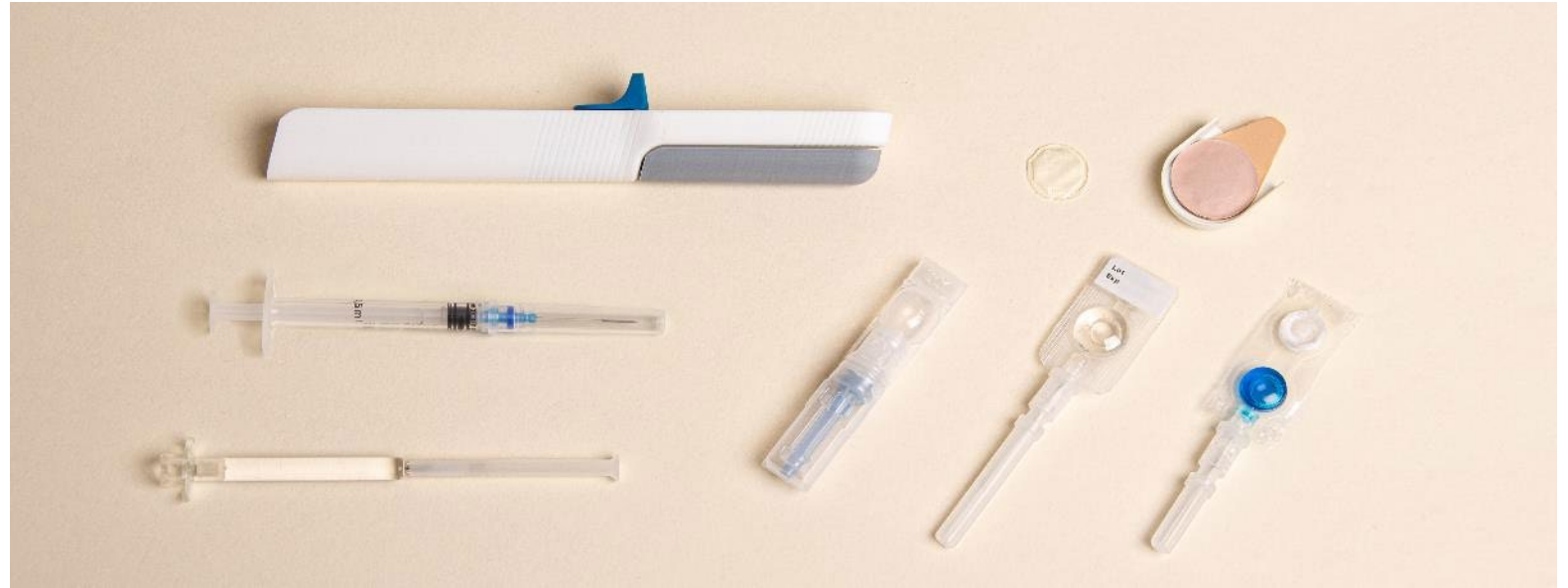
To achieve impact, technologies must be **paired with innovative delivery strategies.**



Source: World Health Organization (WHO)/United Nations Children's Fund (UNICEF). *Immunization Coverage Estimates—2025 Revision*. WHO/UNICEF; 2026.

Abbreviation: DTP3, diphtheria tetanus toxoid and pertussis.

Vaccines innovations to improve vaccine access



Primary containers

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

Delivery devices

- Autodisable sharps-injury protection (AD SIP) syringes
- Liquid inhalers and nebulizers
- Disposable-syringe jet injectors
- Intradermal injection devices

Integrated primary containers and delivery technologies

- BFS multi-monodose (MMD) containers
- Compact prefilled autodisable (CPAD) devices
- Intranasal devices
- Dual-chamber delivery devices
- Solid-dose implants
- Microarray patches (MAPs)
- Sublingual dosage forms
- Oral fast-dissolving tablets

Packaging & safety

- Bundling devices
- Reconstitution vial adapters
- Plastic reconstitution needles

Formulation

- Heat stable and controlled temperature chain (CTC) qualified vaccines
- Freeze damage resistant liquid formulations

Background

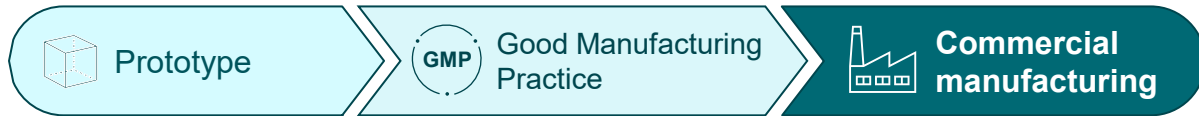
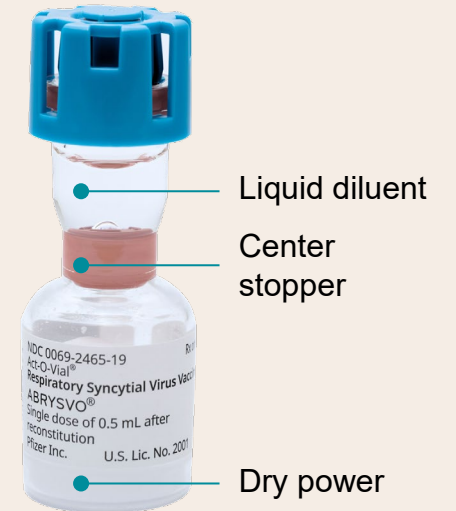
Vaccine innovation case studies

Conclusions

Dual-chamber vial

This is an integrated reconstitution technology for sterile powder and diluent reconstitution of a premeasured dose. Dry powder and liquid diluent are stored in separate compartments of the same device. At the time of administration, the vaccine is reconstituted and administered with a separate delivery device. [ABRYSVO® Act-O-Vial manufactured by Pfizer.]

The dual-chamber vial simplifies reconstitution. To use, press cap to reconstitute a sterile, premeasured dose; mix; and draw the dose.



Device type:				Approved product 	
			Existing GMP fill/finish capability 		
Formulation type:				No overwrap needed 	
				Self-administration N/A	
Dose range (mL): 0.5 mL after reconstitution 				Autodisable N/A	

VALUE PROPOSITION

- **Simplified and safer reconstitution:** This system eliminates reconstitution errors such as contamination or use of the wrong diluent.
- **Ease of activation:** The user depresses the plastic cap to dislodge the internal septum, which forces it into the lower compartment and allows the diluent to flow down and mix with the dry product. Once reconstituted, the dose is withdrawn using a standard needle and syringe.

CONSIDERATIONS

- Typically, more expensive than conventional presentations.
- Not a fully integrated device: After the cap is depressed to mix the diluent with the dry product, a separate, standard needle and syringe still must be used to manually withdraw the reconstituted dose from the vial and administer it to the patient.
- Diluent is required to be stored in the cold chain (larger cold chain volume).

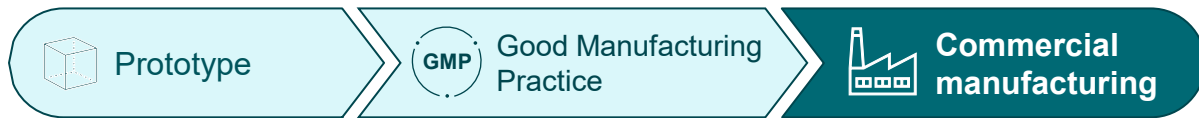
Nasal spray devices

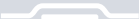
These systems administer liquid vaccine to the upper airways. Operation occurs through pushing the plunger to spray the vaccine into the vaccine recipient's nostrils. For vaccination, devices are typically prefilled, single-use units, but multi-use pump sprays devices have also been evaluated that fit onto a vial. [FluMist manufactured by AstraZeneca.]

Nasal spray devices are needle-free devices that deliver liquid vaccine to the upper respiratory tract.



John Harrington / PR NEWSWIRE



Device type:				Approved product 	
 DELIVERY	 PRIMARY CONTAINER	 COMBINATION PRODUCT	Existing GMP fill/finish capability 		
Formulation type:			No overwrap needed 		
 LIQUID	 DRY POWDER	 DRY POWDER FOR RECONSTITUTION	 IMPLANT	Self-administration 	
Dose range (mL): Varies, 0.2 mL per spray 			Autodisable 		

VALUE PROPOSITION

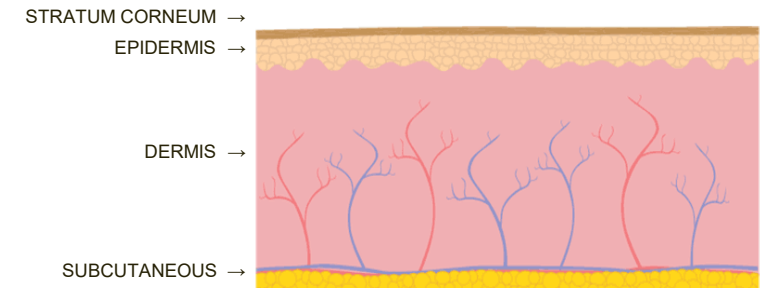
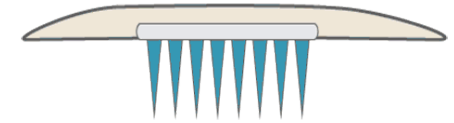
- **Needle-free delivery** eliminates potential injection-site pain and needlestick injuries, as well as the logistical burden of disposing of sharps waste.
- For **at-home use**, patients/caregivers can safely administer due to increased ease of use.
 - In 2024, FluMist was approved for self-administration (18-49 years) and caregiver administration (2-17 years).
 - Vaccine can be ordered online, skipping wait times and need to travel to a pharmacy/health center.
- Respiratory pathogens: Therapeutic impact is maximized by mimicking the **natural route of respiratory infection**.
- Can elicit both systemic and **mucosal immunity**.

CONSIDERATIONS

- Additional contraindications for live-attenuated influenza vaccine (e.g., infants, pregnant individuals, immunocompromised individuals).
- Potential safety risk that intranasal delivery could reach and adversely affect either the cranial nerves or the central nervous system through the olfactory nerve.

Microarray patch (MAP) technology overview

- A patch may have **hundreds or thousands of tiny projections**.
- The projections can be **coated with or composed of a vaccine** (dry formulation).
- **The patch is applied to the skin and pressed down** so that the projections penetrate the top of the skin. The vaccine dissolves in the skin, and the patch can be removed.
- The projections only **penetrate the top layers of the skin** to deliver the vaccine.
- It is typically perceived as **less painful than an injection**.
- Some platforms require an **applicator** for delivery (integrated or separate).
- Vaccine MAPs are in **early-stage clinical development**; it may be a decade or more before a vaccine MAP product could be introduced.



Dissolving MAP



Solid-coated MAP

Measles-rubella (MR) MAPs could increase vaccination coverage for hard-to-reach populations



Attributes

- Ease of use
- No reconstitution
- No needles or sharps waste
- No ancillary supplies
- Enhanced thermostability
- Single-dose presentation



Potential benefits

- Increased acceptability
- Improved safety
- Allows for delivery by lesser-trained health workers
- Controlled Temperature Chain use
- Enables new delivery scenarios (outreach, house-to-house campaigns)
- Reduces missed opportunities for vaccination



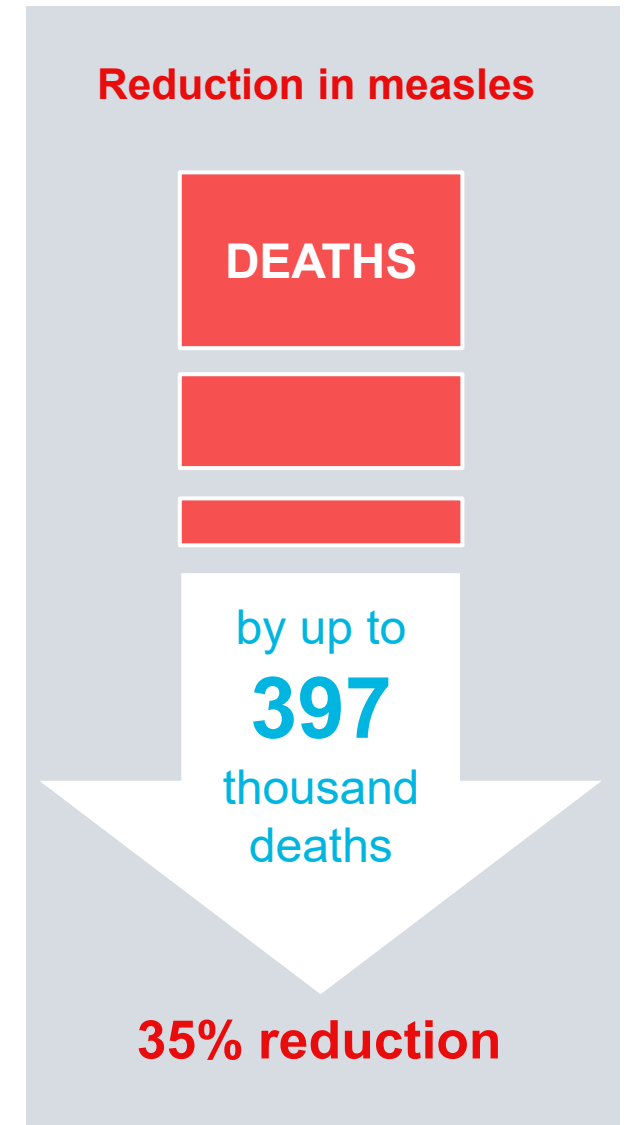
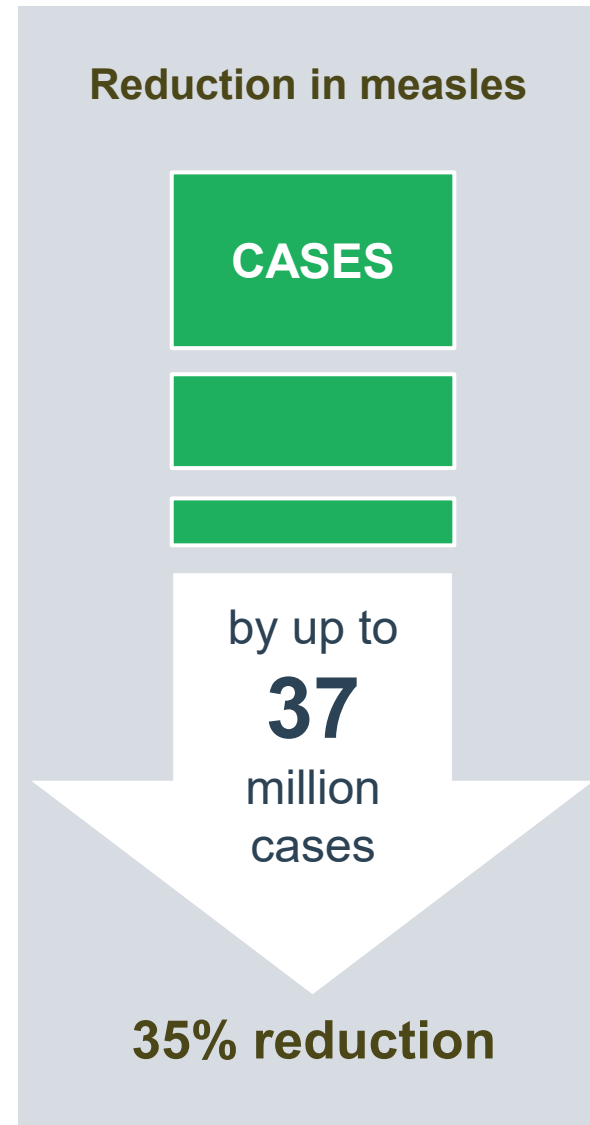
Potential impact

- Increased coverage and equity

MR MAPs could reduce measles burden by 35% and reach 80 million more children between 2030 and 2040.

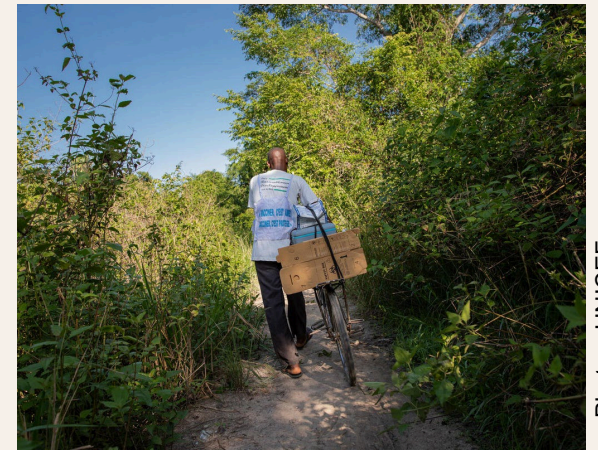
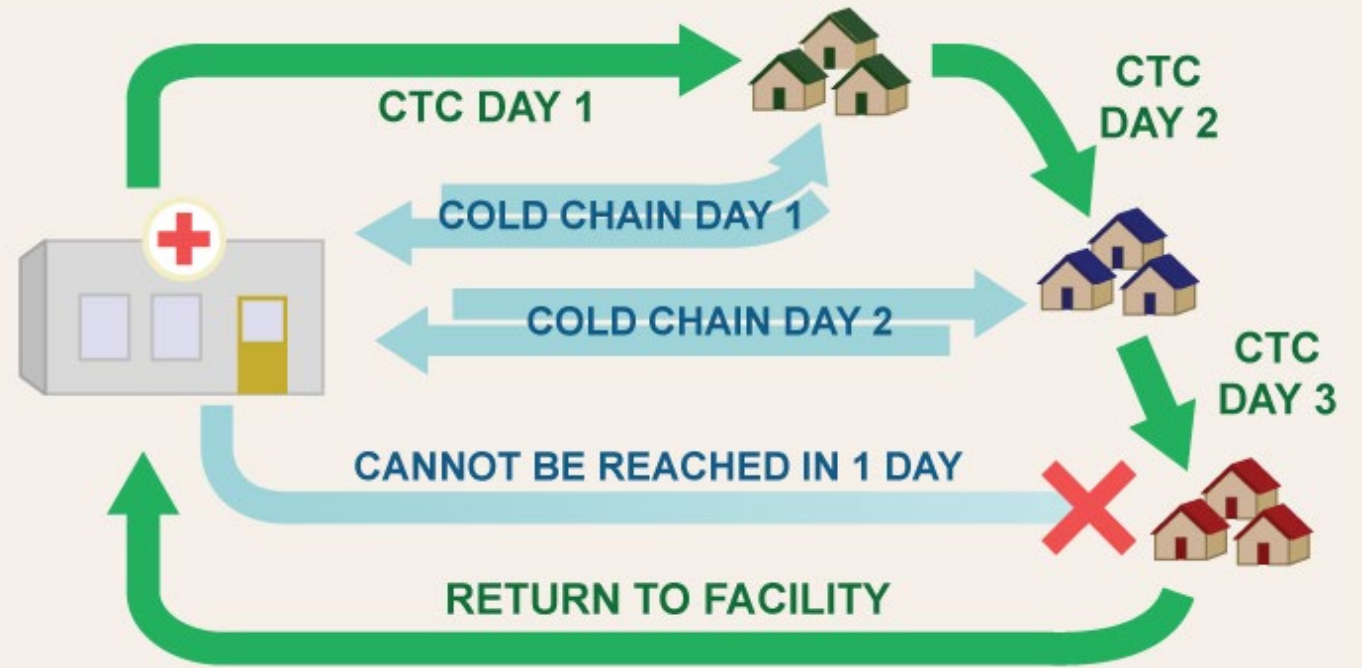


Photo: Micron Biomedical.



Increased reach with CTC MAPs

If MAPs can be stored in a Controlled Temperature Chain (CTC) for at least 3 days at up to 40°C, vaccine access can be improved.



Photos: UNICEF.

Background

Vaccine innovation case studies

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From innovation to impact: What can we do now?

Innovation isn't only what's coming next. Some innovations are already here—but patients and providers need to know about them.

Inform patients



- Tell eligible patients about new ways to access or receive vaccines.
- Explain options that may reduce barriers: self/caregiver administration, fewer preparation steps, simpler delivery.
- Make innovation part of the vaccination conversation: “Here are your options.”



Identify needs

- Track pain points in storage, transport, preparation, administration, and access.
- Ask: *What would make vaccination easier, safer, faster, or more resilient?*



Strengthen readiness

- Keep SOPs, cold-chain practices, inventory systems, and training strong.
- Build flexibility for mobile, surge, and emergency vaccination.



Engage with innovators

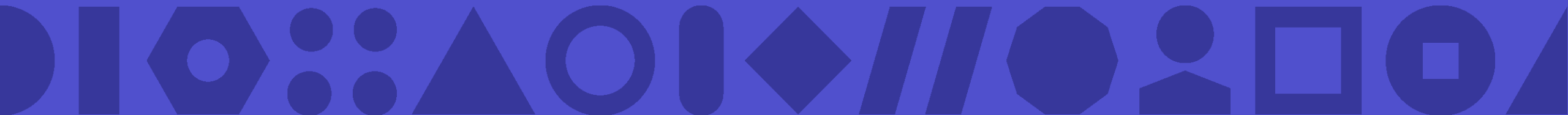
- Participate in pilots, demonstrations, exercises, and implementation studies.
- Give feedback on workflow, usability, training, infrastructure, and patient experience.
- Advocate for innovations with dual markets that address both HIC and LMIC needs.

Questions?

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Appendix

Conventional presentation

- Typically, drugs and vaccines that require mixing have multiple components stored in separate containers (e.g., vial, ampoule).

Potential challenges:

- Multiple preparation steps reduces ease of use and increases training requirements.
- Use errors (e.g., incorrect volume or component mix-up).
- Contamination.
- Needlestick injuries.
- Reuse of reconstitution syringes.
- Stockouts caused by mismatched and/or misallocated quantities of required components.



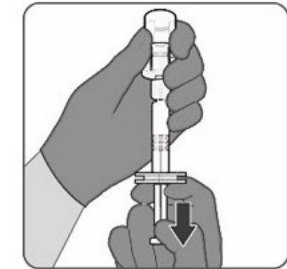
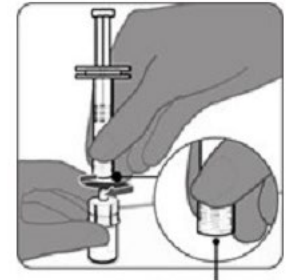
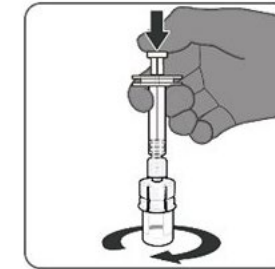
Packaging & delivery technologies that facilitate mixing

Technology category	Description	Stage of development	Example products
Vial adapter  Photo: West Pharmaceuticals	Vial adapters facilitate reconstitution of two vaccine components from their separate primary containers. Their objective is to eliminate the needle from the reconstitution process, making it safer and reducing the number of sharps required.	Commercially available; limited LMIC use	Abrysvo vaccine presentation available as a single-dose vial (lyophilized) co-packaged with prefilled syringe diluent and vial adapter; standalone vial adapters also available.
Bundling devices  Photo: PATH	Devices that allow components to be physically connected or placed together in the same secondary packaging to reduce the possibility of their separation and improve the likelihood of correct preparation and administration.	Commercially available; limited LMIC use	Mosquirix vaccine contains two vials connected with a bundling clip.
Dual-chamber vial  Photo: PATH	Integrated primary container containing dry/liquid components, which are mixed together within the device prior to administration with a separate delivery device.	Various stages of development; no current LMIC use	Pfizer Injectable Act-O-Vial® System on the market for drug and vaccine applications (Solu-Cortef; Solu-Medrol; ABRYSVO)
Dual-chamber delivery device  Image: Vetter	Fully integrated reconstitution technology that is prefilled with dry/liquid components, which are mixed within the device and administered.	Various stages of development; no current LMIC use	- LUPRON DEPT® is stored in a prefilled dual-chamber syringe. - ViATIM® was a liquid-liquid combination vaccine previously available in a dual-chamber syringe.

Abrysvo vial adapter



Whispyhistory / Wikimedia Commons



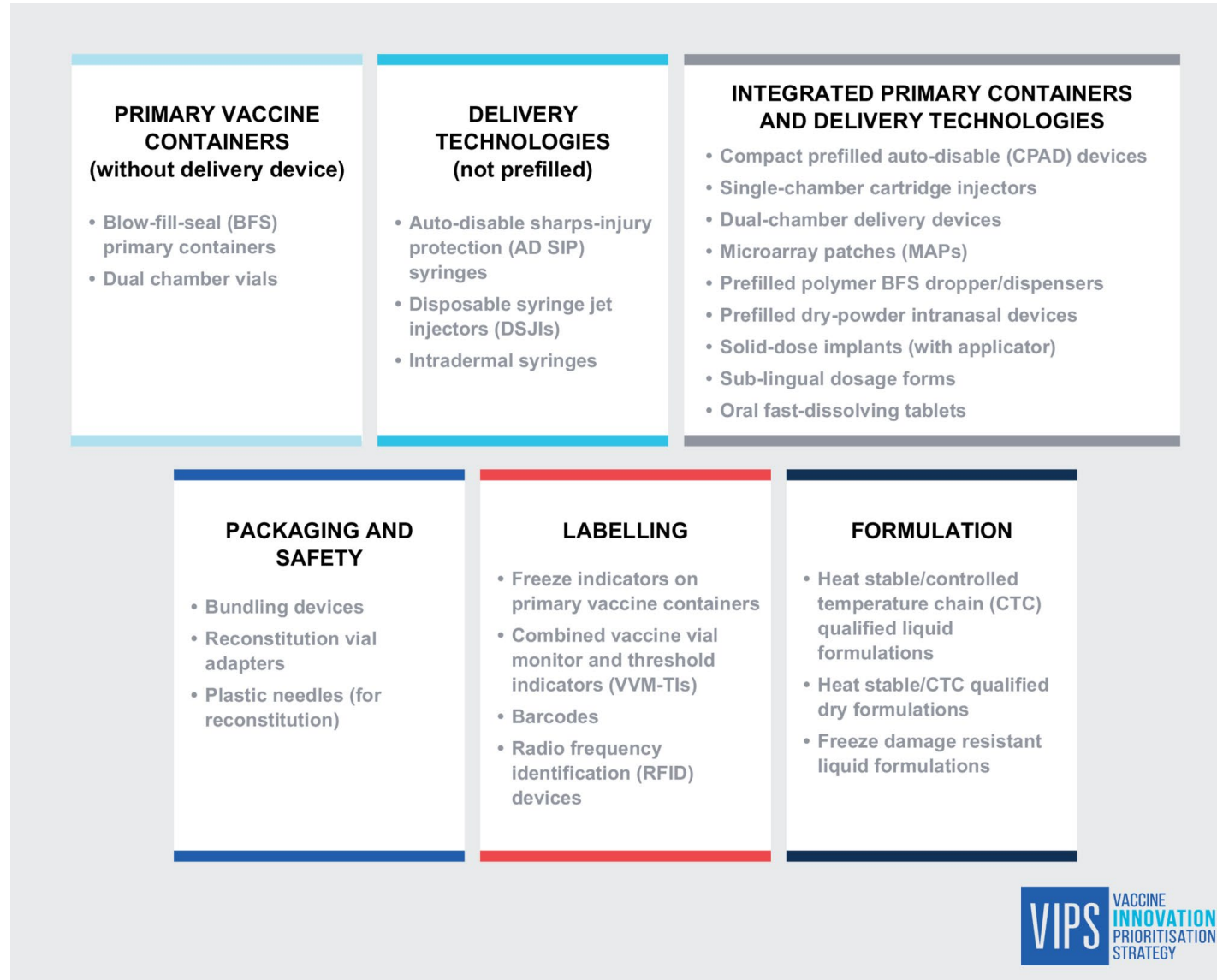
Key implementation barriers identified by country stakeholders*

Category	Implementation barrier	Facility-based (n=268)	Outreach (n=254)	Campaigns (n=298)
Supply chain constraints	Vaccine transport damage	28	62	67
	Shortages due to poor tracking	96	55	57
	Inadequate infrastructure for storage (excluding cold chain capacity)	108 ^b	61	68
	Insufficient cold chain capacity	65	42	70
	Shortages of commodities required for administration	56	38	36
	Wastage due to heat exposure	22	62	92
	Wastage due to freeze exposure	26	13	18
	Damage due to inappropriate storage	36	41	62
Geographic and socioeconomic constraints	Geographic barriers (e.g., remote populations)	100	147 ^a	126 ^a
	Social barriers (e.g., marginalized populations requiring greater outreach)	82	121 ^b	125 ^b
	Financial barriers	71	49	27
Vaccine acceptability or vaccine hesitancy constraints	Mistrust in health care workers	24	44	93 ^c
	Fear of injections and needles	64	60	59
	Discomfort after vaccination	69	54	81
Healthcare service provider constraints	Lack of available health care workers	101 ^c	110 ^c	65
	Lack of training and skills	75	55	85
Other immunization service delivery related constraints	Missed opportunities due to complexity of vaccine preparation and/or administration	35	27	26
	Missed opportunities due to reluctance to open multi-dose vials	126 ^a	81	37

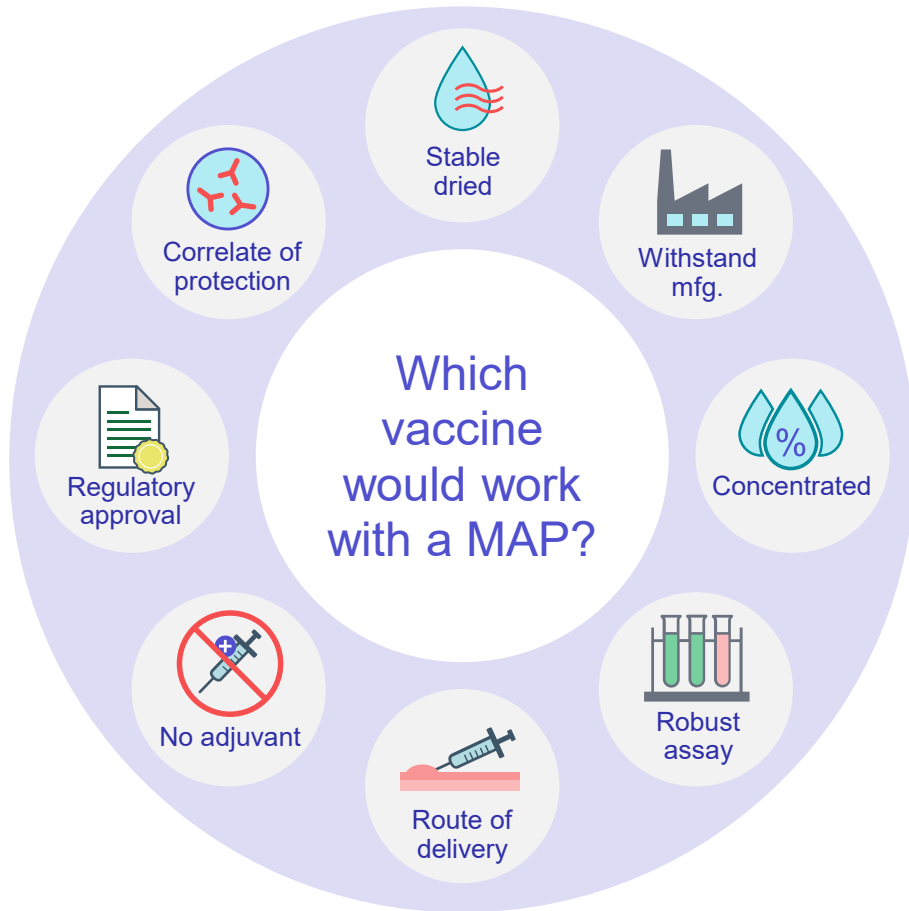
*Mvundura et al. 2021 (*Vaccine*); survey conducted on behalf of the Vaccine Innovation Prioritisation Strategy (VIPS)

Rankings of responses, the darkest being highest reported potential benefit.

Example vaccine innovations to improve vaccine access

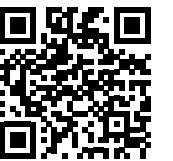


Vaccine antigen qualities for microarray patches



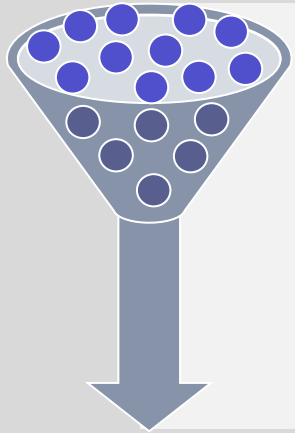
	Is the antigen stable when dried ?	Antigens that can be dried or lyophilized with minimal excipients are best suited to the MAP manufacturing process.
	Is the antigen robust to withstand manufacturing?	During the manufacturing process, the antigen may be exposed to elevated pressures, velocities, or temperatures. Labile antigens may still be used in MAPs but may require longer processing times or require more complex manufacturing.
	Is the antigen able to be concentrated ?	The bulk antigen should be concentrated such that a full dose is present in approximately 10 µl or less.
	Is there a robust assay for the antigen?	A robust potency assay is needed during formulation screening and process development.
	What is the route of delivery of the antigen?	Data demonstrating intradermal vaccination is immunogenic increase the chance of success for a MAP. Oral vaccines may not be suitable for MAP delivery.
	Does the antigen require an adjuvant ?	Adjuvants may increase the local reactogenicity following MAP vaccination, and adjuvants commonly used in liquid vaccines can be difficult to formulate in a MAP. Novel adjuvants may be necessary if an adjuvant is indicated.
	Is the antigen approved by a regulatory authority?	Both a novel antigen and novel delivery method may increase complexity to achieve regulatory approval.
	Does the antigen have a correlate of protection ?	Correlates of protection or other immunological end points may accelerate clinical development.

Antigen prioritization process



Frivold et al. 2025
(Vaccine)

REFERENCE LIST: 91 vaccine targets



Background research on key attributes:

- Vaccine target information (including route of administration)*
- Market distribution (has LMIC market)*
- Known global/regional health organization interest*
- Specific global health priority/agenda*
- Status of vaccine development*
- Populations/use settings for MAPs*
- Known interest in the vaccine MAP
- Potential MAP benefits
- Technical and regulatory success

**Attribute used for down-selection*



INTERIM LIST: 21 vaccine targets identified based on first stage of prioritization process

Feedback from external advisory group



PRIORITY LIST: 11 vaccine targets for use in LMICs

11 vaccine targets categorized into two priority groups based on:

- ▶ Potential programmatic impact
- ▶ Financial sustainability or funders' interest

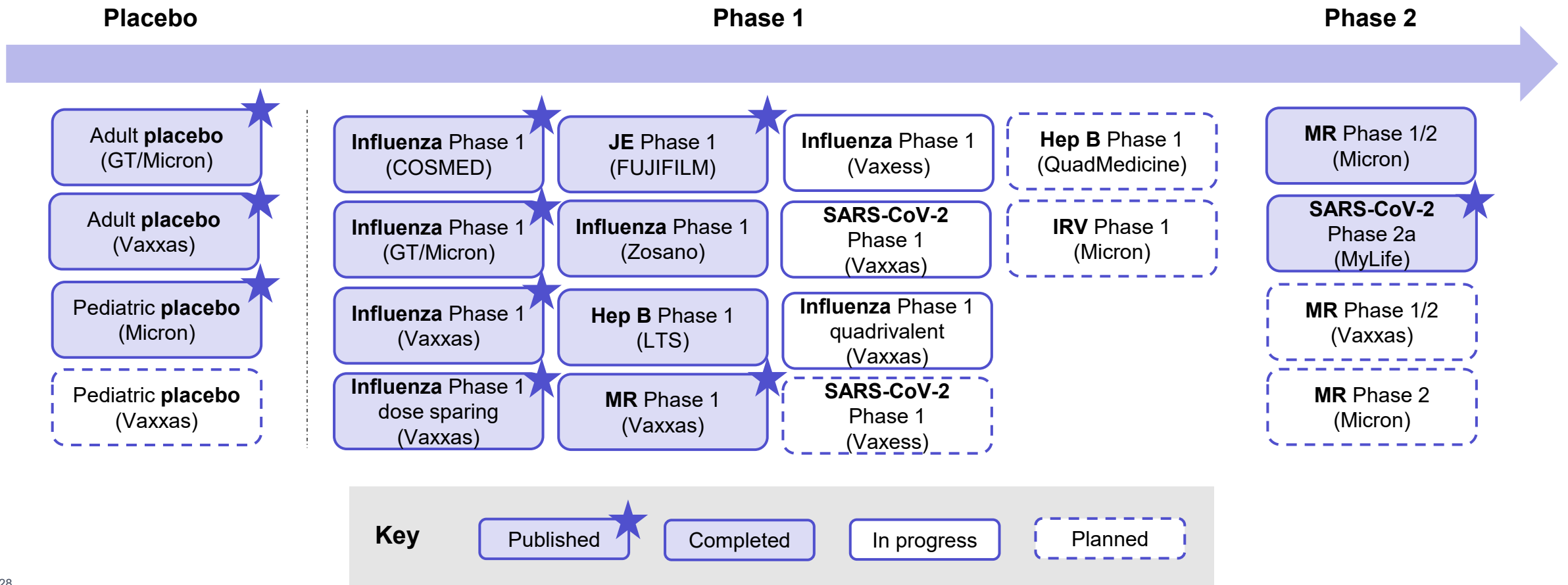
VIPS priority list of vaccine microarray patches for LMICs

PRIORITY GROUP 1:	PRIORITY GROUP 2:
• Hepatitis B virus • Measles, rubella/measles, mumps and rubella viruses • Human papillomavirus • Rabies virus • Yellow fever • Influenza virus (seasonal and pandemic) • SARS-CoV-2	• Group B streptococcus • <i>Neisseria meningitidis</i> A,C,W,Y,(X) • <i>Salmonella</i> Typhi • <i>Streptococcus pneumoniae</i>

Abbreviations: LMIC, low- and middle-income country; MAP; microarray patch; VIPS, Vaccine Innovation Prioritisation Strategy.

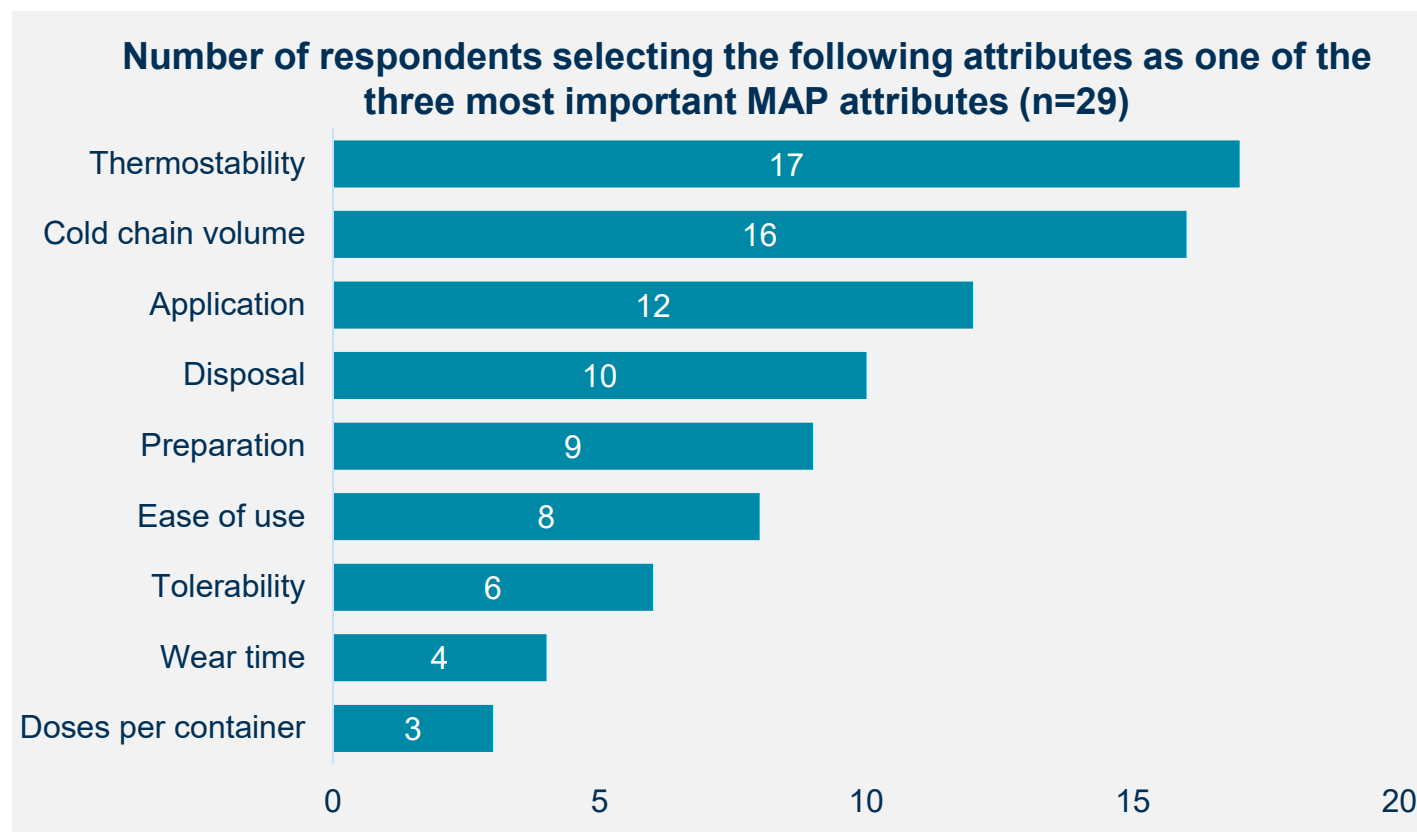
The clinical evidence base for vaccine MAPs is expanding

Results are published or anticipated for the measles-rubella (MR) vaccine, inactivated rotavirus vaccine (IRV), and the vaccines for influenza, COVID-19 virus (SARS-CoV-2), hepatitis B (Hep B), and Japanese encephalitis (JE) in Phase 1, as well as Phase 2 for MR and SARS-CoV-2.



Abbreviations: GT, Georgia Institute of Technology; LTS, Lohmann Therapie-Systeme.

Most important MAP product attributes



Q. Besides effectiveness and safety, which of the MAP product attributes listed in the product concept card are the three most important? Can you briefly explain why those attributes are the most important?

Observations

- Beyond safety and effectiveness, respondents reported **thermostability**, **cold chain volume**, and **application** most frequently as the most important MAP attributes.*
- Several stakeholders commented that they considered all the MAP attributes to be important and valuable for vaccine delivery.
- Reasons cited for importance include:
 - Thermostability:** Could increase access among HTR populations; address heat sensitivity of current vaccines and reduce cold chain requirements; facilitate CTC use.
 - Cold chain volume:** Stakeholders emphasized that current cold chain capacity is limited; the potential impact of the MAP cold chain volume on cold chain capacity will be an important factor when considering whether to introduce MAPs.
 - Application:** Feature to prevent accidental reuse was noted as a key benefit; application process could improve ease of use.

*See slide 11 for definitions of the MAP attributes.