VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

# Identification of priority vaccines for micro-array patches (MAPs) and CTC use

Public Consultation

January 2023

Gavi The Vaccine Alliance

World Health Organization

BILL & MELINDA GATES foundation

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**The Vaccine Innovation Prioritisation Strategy (VIPS)** is a global partnership between the Gavi Secretariat, World Health Organization (WHO), United Nations Children's Fund (UNICEF), Bill & Melinda Gates Foundation (BMGF) and PATH – known as the VIPS Alliance – to prioritise and drive vaccine product innovation to increase equitable vaccine coverage in low- and middle-income countries and contribute to global health security.

# VIPS has prioritised 3 innovations with the broadest public health benefits and applicability that can help better meet country needs & contribute to coverage and equity goals

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

**2018-2020**

The VIPS Alliance has assessed and **prioritised a long list of vaccine product innovations** using an evaluation framework and incorporating country and expert inputs

**Current**

As a next step, the VIPS Alliance is **supporting the prioritised innovations to accelerate development and country uptake in LMICs**

**Long term Impact**

The work of the VIPS alliance aims to contribute to **increased equitable coverage**, including reaching zero-dose children and **increased global health security preparedness and response**

## Prioritised Innovations

**Microarray patches**

**Heat stable and CTC qualified vaccines**

**Barcodes on primary packaging**



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# VIPS has conducted a vaccine prioritisation exercise to identify priority vaccines for microarray patches (MAPs) and CTC use

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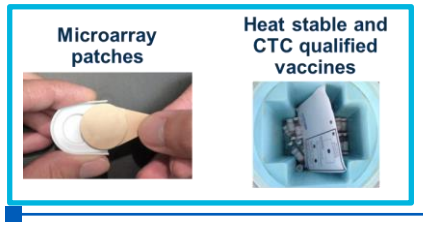
**3 innovations prioritised by VIPS** from an initial list of 24, with the potential to better meet country needs and increase equitable immunisation coverage





**Consultations with manufacturers and developers** revealed the **need for clearer guidance on priority vaccines** for MAPs and CTC use

**VIPS Vaccine Prioritisation** to identify vaccines relevant to LMICs for which **MAPs and CTC use** would be **most valuable from a programmatic perspective**, as well as **technically feasible**

**Focus of this consultation**

The outcomes of this exercise will be signaled to **inform investment decisions** by industry and partners and will inform **VIPS future activities for MAPs and CTC**

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# High-level methodology used for the vaccine prioritisation for both MAPs and CTC

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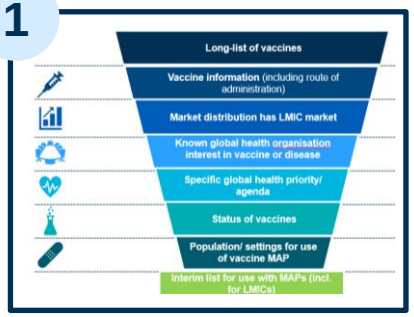



**Systematic assessment of key indicators** across landscape of vaccines to identify an interim list of vaccine targets for further assessment

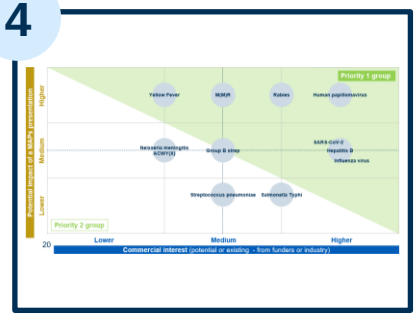
**2**

**Expert feedback** on interim list of vaccine targets for use with MAPs and CTC

**3**

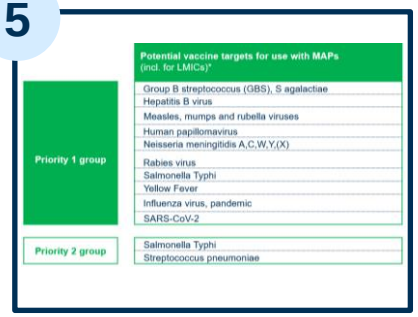
Evaluation of the expected **complexity of the regulatory pathway (MAPs Only)**

**4**



**Prioritisation of vaccine targets** based on potential programmatic **impact and financial sustainability/ funders interest**

**5**




**VIPS priority lists of vaccine targets** for use with MAPs and CTC relevant to LMICs

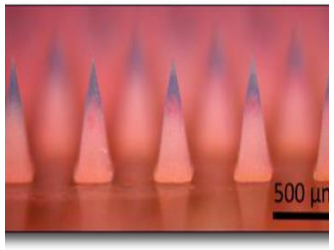
# Contents

# Background on Microarray Patches (MAPs)

- MAPs consist of **an array of micro-projections on a patch**. The micro-projections are coated with or are composed of, vaccine in a dry formulation. When a MAP is applied to the skin, the vaccine is delivered into the dermis and/or epidermis layers.
- **MAPs offer many potential programmatic benefits for vaccine delivery** including ease of use, safety, improved acceptability, enhanced thermostability, single dose presentation, no syringe and glass vial, dose-sparing and possibly faster immune responses.
- **MAPs furthest along in development are in Phase 1/2 clinical trials** (Measles-rubella, seasonal influenza, COVID).

Vaxxas, 15 May 2019

micronbiomedical.com [b]




WHO [c]

# The methodology and outcomes of the vaccine prioritisation exercise for MAPs have been validated through expert consultation

The VIPS vaccine priority list for MAPs has been validated with WHO and other programmatic experts and is now shared for public consultation.

1

## WHO CONSULTATION

- Provided feedback on methodology and VIPS vaccine priority shortlist and final list for MAPs

2

## EXPERT CONSULTATIONS

- Provided feedback on the methodology, VIPS vaccine priority shortlist and final list for MAPs, including inputs on programmatic impact and tradeoffs to inform the VIPS priority vaccine targets list

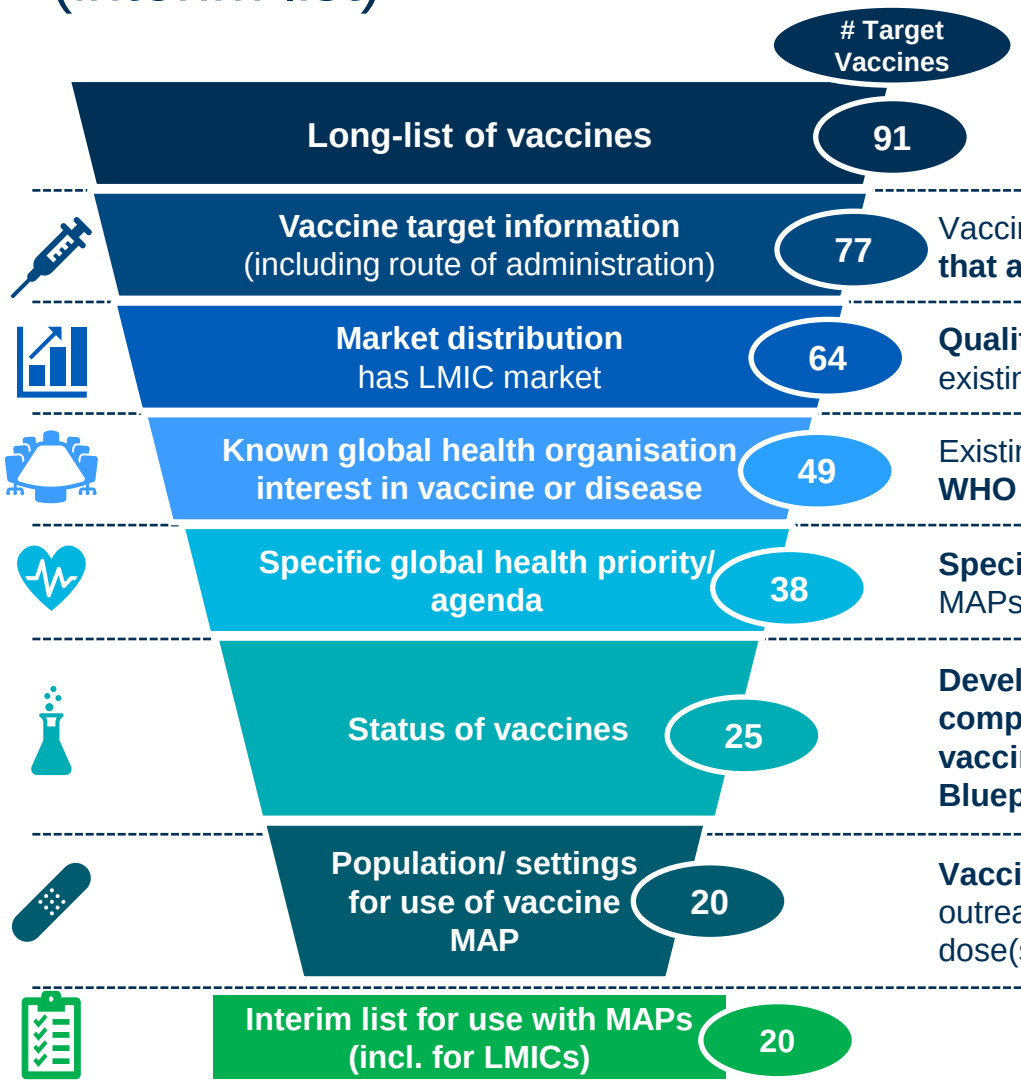
3

## PUBLIC CONSULTATION

- To provide an opportunity to individuals from broad stakeholder groups to provide feedback on the VIPS vaccine priority list for MAPs

# Methodology overview to prioritise vaccines for MAPs (interim list)

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY




Vaccine target or pathogen/disease, vaccine type and **administration route – selecting only vaccines that are delivered through intradermal, intramuscular or subcutaneous routes**

**Qualitative assessment** of whether there is a potential market **for the vaccine in LMICs** based on existing knowledge and literature review regarding burden of disease, epidemiology or existing markets.

Existing interest of one of the following global public health organisations or committees: **WHO PDVAC, WHO PDR, WHO R&D Blueprint, Gavi, UNICEF, CEPI, CARB-X, BARDA, other funders and PPPs.**

**Specific global health needs** that have already been identified and could benefit most from vaccine MAPs: **elimination agenda, epi/ pandemic potential and risk of AMR.**

**Development stage**: preclinical, phase1, phase 2, phase 3, licensed and PQ. Only **vaccines that have completed phase 3 are selected, except for vaccine targets with outbreak potential,** where **vaccines having completed phase 2 only are also selected if they are amongst CEPI or R&D Blueprint priorities** focusing on disease with epidemic potential.

**Vaccination settings or target populations:** RI – usually at fixed health post, or 'special settings' i.e. outreach/campaign, birth-dose, adolescents/ adults, maternal, older adults, travel/migrants or booster dose(s). **Only special settings are selected.**

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# Expert feedback narrowed down the interim list of 20 vaccines to 11 priority vaccines for MAPs

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

| | Interim list of 20 vaccine targets for use with MAPs (incl. for LMICs) | Inclusion in final list | Feedback from Expert Group: rationale for excluding from the list |
|---|---|---|---|
| **Legacy** High volumes of vaccines available with low unit price | **Hepatitis B virus** | ✓ | |
| | **Measles, mumps and rubella viruses** (MR and MMR) | ✓ | |
| | **Mycobacterium tuberculosis** (BCG) | X | The **low price point of BCG** makes it an unfavorable target for MAPs |
| | **Poliovirus, inactivated** | X | In the next 10 years it is likely that there **will not be a large market for IPV as a standalone** as it may be replaced by **Hexavalent** vaccine. |
| | **Rabies virus** | ✓ | |
| | **Salmonella Typhi** | ✓ | |
| | **Yellow Fever** | ✓ | |
| **Evolving** Not commoditised/ higher price vaccines, or vaccines still in development | **Group B streptococcus** (GBS), S agalactiae | ✓ | |
| | **Human papillomavirus** | ✓ | |
| | **Malaria** | X | There is **no surrogate of efficacy identified** for this target, so it would be a very risky choice from a development perspective |
| | **Mycobacterium tuberculosis** (next generation) | X | There is **no surrogate of efficacy identified** for this target, so it would be a very risky choice from a development perspective |
| | **Neisseria meningitidis A,C,W,Y (X)** | ✓ | |
| | **Streptococcus pneumoniae** | ✓ | |
| **Outbreak** Vaccine targets with unpredictable demand driven by outbreaks | **Chikungunya virus** | X | All **outbreak vaccines present a very challenging business case**, and some are still at a relatively early development stage.<br>**Clinical trials are also complex** as for some of these targets, having enough cases/ transmission to conduct a clinical trial can be challenging.<br>Therefore, **only influenza (pandemic and seasonal) and SARS-CoV-2** will be kept as representative antigens of outbreak vaccines as they are **also either used in endemic settings or will likely be.** |
| | **Ebola virus** | X | |
| | **Influenza virus, pandemic** | ✓ | |
| | MERS coronavirus (MERS-CoV) | X | |
| | **Rift Valley fever virus** (RVF) | X | |
| | **SARS-CoV-2** | ✓ | |
| | **Zika** | X | |

# Additional considerations on MAPs regulatory pathway, potential programmatic impact and financial sustainability/ funders interest were taken into consideration

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

| | Potential vaccine targets for use with MAPs | Estimated regulatory pathway complexity | Potential programmatic impact | Potential financial sustainability or funders interest |
|---|---|---|---|---|
| **Legacy** High volumes of vaccines available with low unit price | **Hepatitis B virus** | *Low* | *Moderate-high* | *High* |
| | **Measles and rubella viruses** | *Low* | *High* | *Medium* |
| | **Measles, mumps and rubella** | *Medium* | *High* | *High* |
| | **Rabies virus** | *Low* | *High* | *Medium-high* |
| | **Salmonella Typhi** | *Medium* | *Low* | *Medium-high* |
| | **Yellow Fever** | *Medium* | *High* | *Medium-low* |
| **Evolving** Not commoditised/ higher price vaccines, or vaccines still in development | **Group B streptococcus** (GBS), S agalactiae | *High* | *Moderate* | *Medium* |
| | **Human papillomavirus** | *Medium* | *High* | *High* |
| | **Neisseria meningitidis A,C,W,Y** | *Medium* | *Moderate* | *Medium-low* |
| | **Neisseria meningitidis A,C,W,Y,X** | *Medium* | *Moderate* | *Medium-low* |
| | **Streptococcus pneumoniae** | *Low* | *Low* | *Medium* |
| **Outbreak** Vaccine targets with unpredictable demand driven by outbreaks | **Influenza virus, pandemic and seasonal** | *Medium* | *Moderate* | *High* |
| | **SARS-CoV-2** | *Medium* | *Moderate* | *High* |

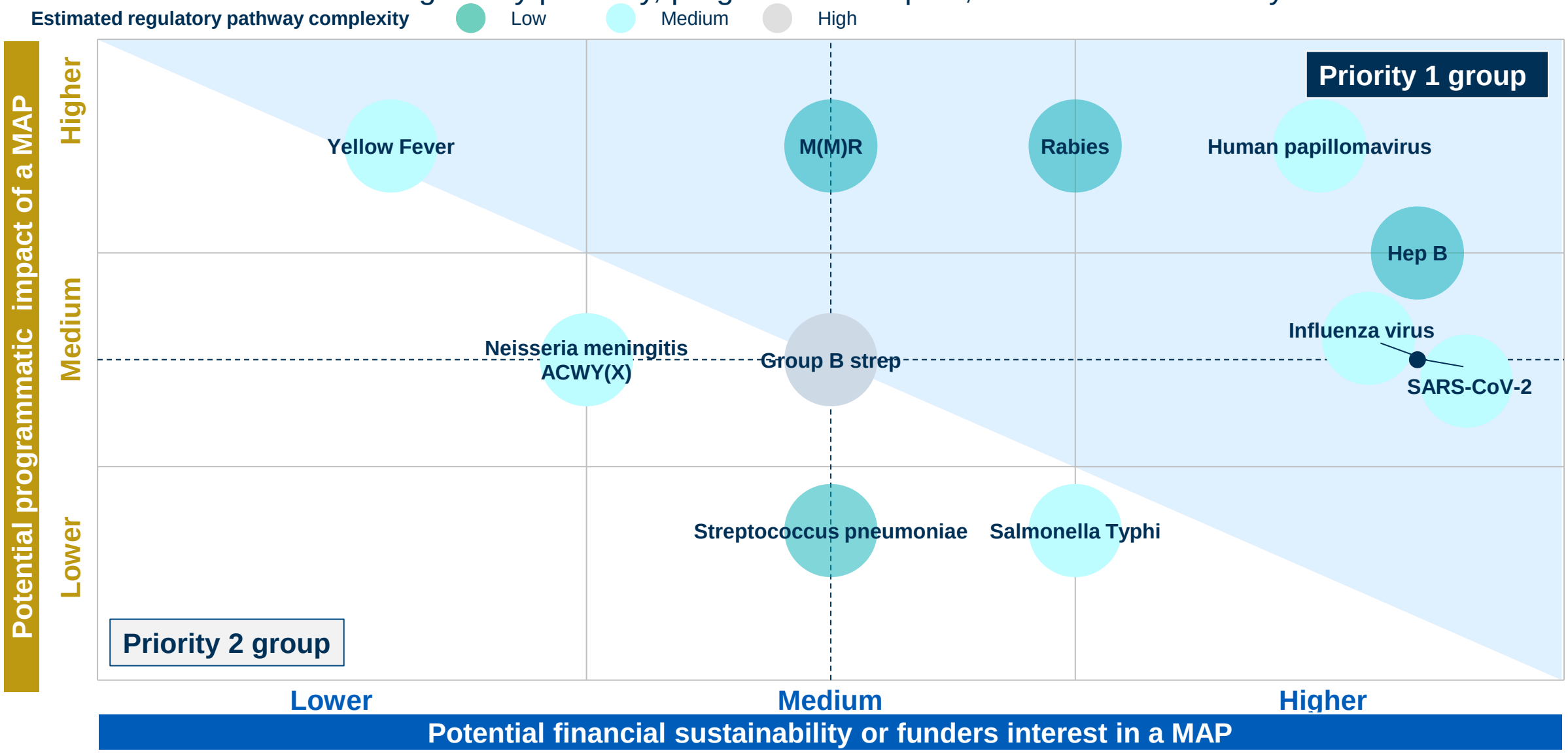


Additional details on assessments in appendix.

# The additional considerations allowed to define two groups within priority vaccines for MAPs

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

## Additional considerations: regulatory pathway, programmatic impact, financial sustainability/ funders interest



# Proposed VIPS priority list of vaccine targets for MAPs

| | PRIORITY LIST of vaccine targets for MAPs |
|---|---|
| **Priority 1 group** | 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** | Group B streptococcus (GBS), S agalactiae |
| | Neisseria meningitidis A,C,W,Y,(X) |
| | Salmonella Typhi |
| | Streptococcus pneumoniae |

Please share your feedback on above prioritisation of vaccines for MAP use.

# Contents

# Background on CTC

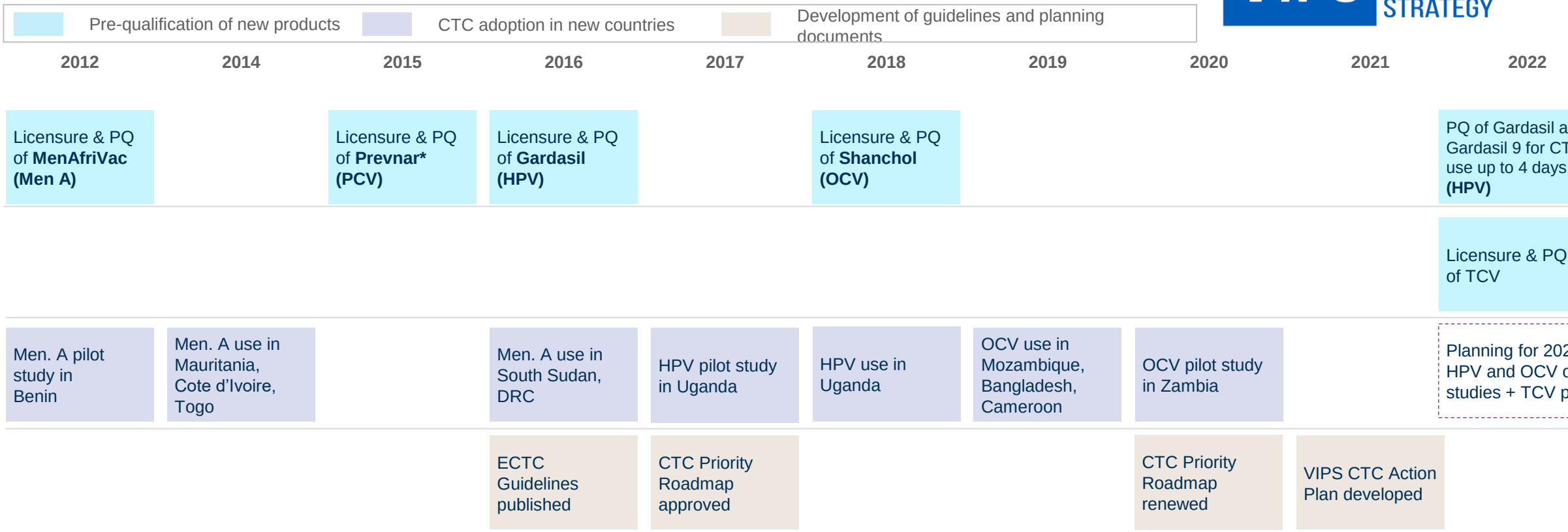
- The “controlled temperature chain” (CTC) is a validated approach to vaccine management and handling allowing qualified vaccines to be kept at temperatures **above of the traditional cold chain** of +2°C to +8°C for a **specified period of time** under monitored and controlled conditions, as appropriate to the stability of the antigen.[1]
- WHO’s current criteria  for vaccines labelled for and used in a CTC include the following:
  - The vaccine should be used in a **campaign or special strategy setting.** CTC is not currently recommended for immunization through facility-based routine delivery or when outreach activities are integrated with vaccines still requiring the cold chain.
  - The vaccine must be able to tolerate ambient temperatures of at **least +40°C  for a minimum of three days** and should be accompanied by
    - a v**accine vial monitor (VVM)** on each vial, and
    - a **peak threshold temperature indicator (PTTI)** in each vaccine carrier.
  - The vaccine must be licensed for intentional use in a CTC by the relevant regulatory authorities, with a **package insert** that specifies the conditions.

*1 https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/ctc/*

*2. 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*

# Summary of CTC qualification status

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY




Since the innovation was first introduced in 2012, 4 vaccines[2] have been labelled for CTC use, and the innovation has been adopted by 11 countries:

- **MenAfriVac® meningococcal A (Men A)** conjugate lyophilized vaccine from Serum Institute of India Pvt. Ltd.: Qualified in 2012 for "up to 4 days at ambient temperatures not exceeding 40°C".
- **Gardasil® 4 quadrivalent liquid human papillomavirus (HPV)** vaccine from Merck: Qualified in 2016 "for 72 hours when stored at temperatures from 8°C to 42°C". A recent PQT approval for Gardasil and Gardasil 9 to be "96 hours at storage temperature from 8°C to 40°C".
- **Shanchol™ liquid oral cholera vaccine (OCV)** from Shantha Biotechnics: Qualified in 2018 "for up to 14 days at ambient temperatures not exceeding 40°C".
- **Typbar TCV® (Typhoid Vi Conjugate Vaccine) 5-dose from** Bharat Biotech International Limited: Qualified in 2022 for up to 3 consecutive days at temperatures not exceeding 55°C; or up to SEVEN consecutive days jat temperatures not exceeding 40°C.

**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*

# The methodology and outcomes of the vaccine prioritisation exercise for CTC have been validated through country and expert consultation

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

1

## COUNTRY CONSULTATION

- To understand priority vaccines for CTC use

2

## PROGRAMMATIC EXPERT CONSULTATIONS

- To provide feedback on the methodology and VIPS vaccine priority shortlist and final list for CTC including programmatic impact

3

## EXPERT CONSULTATION

- To provide feedback on the methodology, VIPS vaccine priority shortlist and final list for CTC and next steps

4

## PUBLIC CONSULTATION

- To provide an opportunity to individuals from broad stakeholder groups to provide feedback on the VIPS vaccine priority list for CTC

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# The scope of the prioritisation exercise has been defined by the heat stability data available for the assessment

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**1**

## ✓ Licensed vaccines

- Stability data **available** to access

**2**

## ✓ Near-licensure vaccines

- Stability data **available** to access in most cases
- For some vaccines such as Men A, C, W, Y, (X) and novel oral poliovirus, **stability data are assumed to be similar to existing vaccines** (Men A and OPV respectively)

**3**

## Pipeline vaccines

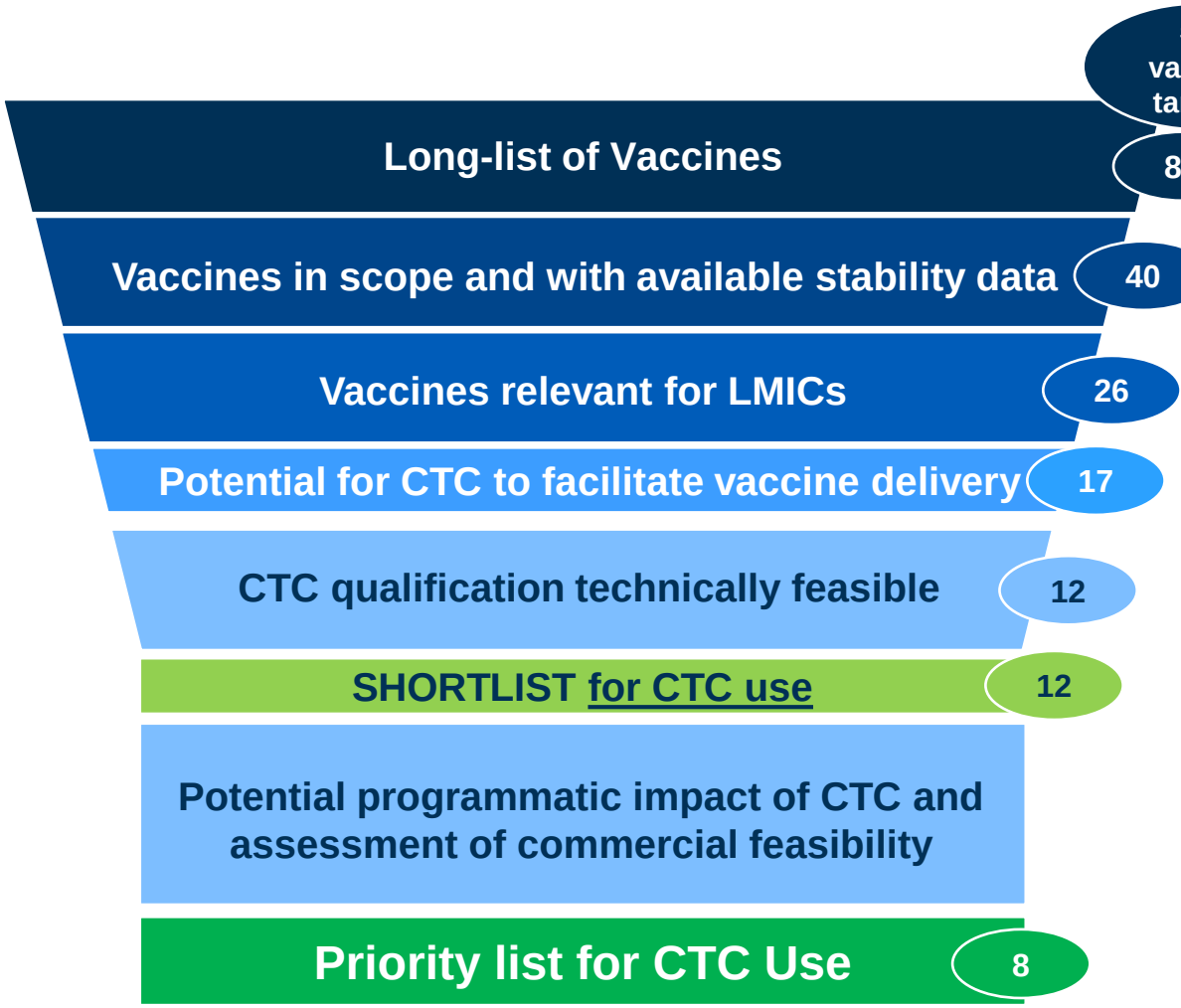
### ✓ Important for epidemic/ pandemic preparedness

- Vaccines on the **WHO R&D Blueprint** or **CEPI list are included** as these vaccines are typically developed during an outbreak with no time to work on thermostability, hence communicating upfront needs is important
- Only vaccines that have successfully completed **phase 2 clinical trials are included** due to higher probability of success.
- The following vaccines fit the criteria above but **no data was found** on the heat stability of these vaccines, hence they were not included in the analysis:
  - × MERS-CoV
  - × Rift Valley fever
- The following vaccines fit the criteria above and **stability data was found** and hence included in the analysis:
  - ✓ **Chikungunya**
  - ✓ **Rotavirus (next generation)**
  - ✓ **Zika**

### × Remaining pipeline vaccines (not assessed)

- Stability data unavailable or hard to access
- Some of the remaining pipeline vaccines are accounted through the inclusion of **innovative vaccine platforms** in the final priority list for heat-stability improvements. For such platforms, the experience of improving heat stability for the platform through currently licensed vaccines can be applied to other vaccines produced on the same platform, including some upcoming pipeline vaccines (e.g., Nucleic acid vaccine production platforms and Viral vector vaccine production platforms).
- In addition, the preferred product stability and storage requirements for pipeline vaccines are addressed in **WHO PPCs.**

# Methodology overview to prioritise vaccines for CTC use




- Includes licensed, near-licensure vaccines and some pipeline vaccines (i.e., those on R&D blueprint or CEPI list and have completed phase 2 clinical trials)
- Excludes vaccines that are **obsolete**, **not used/ recommended** in LMICs or not on any **stakeholder's priority lists**, poised to be **replaced** by another vaccine or no longer being **procured**.
- Vaccine delivery in **campaigns/ outbreaks or through special strategies**
- Whether CTC qualification is feasible based on **existing heat stability/VVM classification only**; assumes **no reformulation work**. Combination vaccines are assumed technically complex to improve for heat stability due to individual components.
- **Potential programmatic impact** based on greatest perceived benefits and potential use case for CTC use; perceived challenges and feasibility of implementation based on previous VIPS consultations, CTC country consultations and programmatic expert consultation
- **Potential commercial feasibility** based on prioritisation/ funding of vaccines by Gavi or CEPI, LMIC market and known manufacturer interest in CTC.

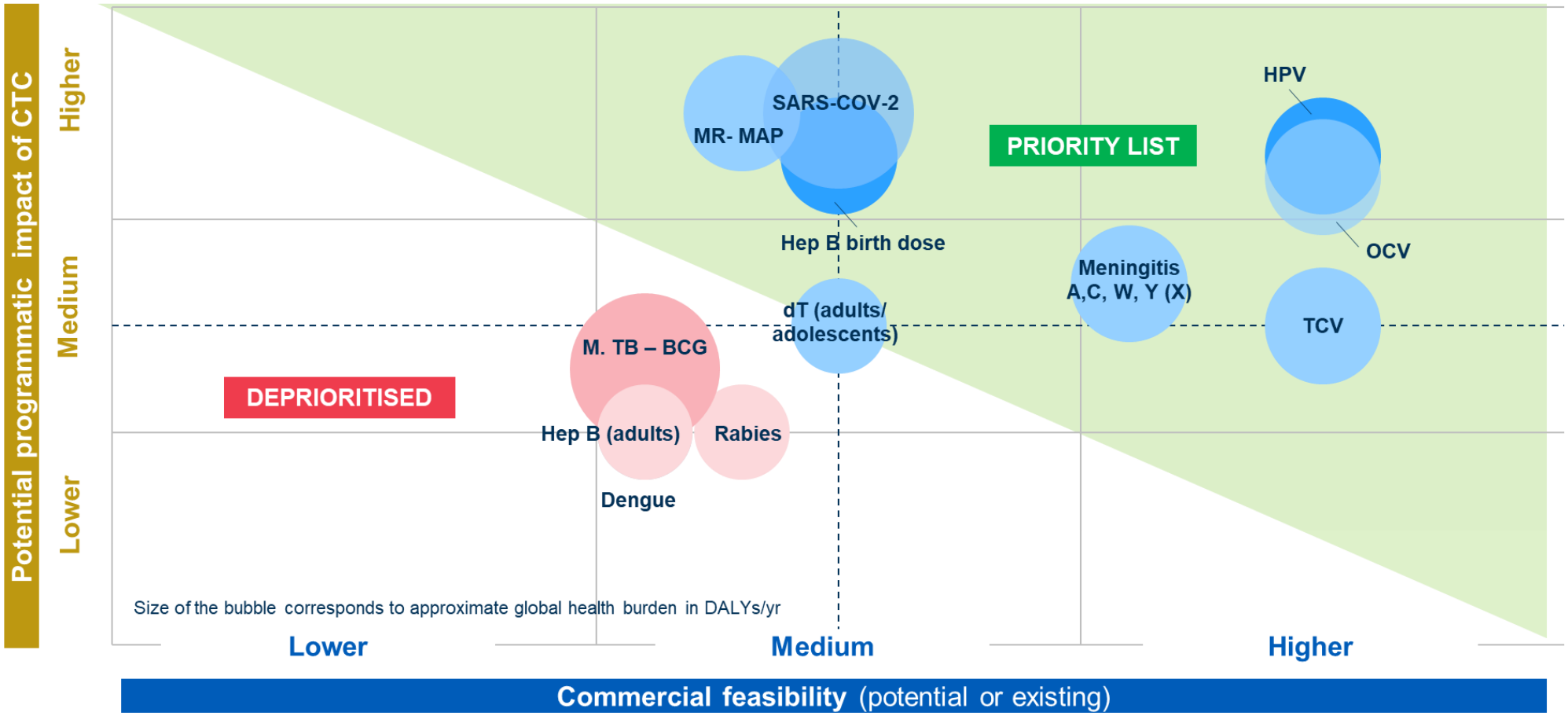
# VIPS vaccine target shortlist for CTC use

| **CTC SHORTLIST** in alphabetical order |
|---|
| Dengue |
| dT (reduced d antigen for adults/adolescents) |
| Hepatitis B (birth dose) |
| Hepatitis B (adults) |
| Human papillomavirus (HPV) |
| Measles-Rubella (MR)- MAP[1] |
| Meningitis A,C, W, Y (X) |
| M.Tuberculosis – BCG |
| Oral Cholera Vaccines (OCV) |
| Rabies |
| SARS-COV-2 |
| Typhoid conjugate vaccine (TCV) |

[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*

# Looking at both programmatic impact and commercial feasibility provided a CTC priority list of 8 vaccine targets

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY



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# Proposed VIPS priority list of vaccine targets for CTC use

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

| **CTC PRIORITY LIST** 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) |

Please share your feedback on the prioritisation of antigens for CTC use.

[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*

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

# Appendices

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# Applying the filtering criteria to prioritise vaccines for MAPs – Illustrative examples

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| Example vaccine targets | | Vaccine information | | Market distribution has LMIC market | Known global health organisation interest | | Specific global health priority/ agenda | | Status of vaccines* | | Population/ settings for potential use of vaccine MAP | | Inclusion in interim list |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Vaccine target | Vaccine type | | | | | | | | | | | | |
| **Human papillomavirus (HPV)** | Subunit (VLP) | ✓ | IM | ✓ | ✓ | Funded by Gavi, procured by UNICEF and PAHO | ✓ | WHO's Global Strategy to Accelerate the Elimination of Cervical Cancer | V | PQ/ EUL or licensed | ✓ | Adolescents/ or adults and introduction campaigns | YES |
| | Subunit | ✓ | IM | ✓ | X | | ✓ | | X | Phase 1 | ✓ | Adolescents/ or adults | |
| | Subunit, peptide | ✓ | IM | ✓ | X | | ✓ | | X | Phase 2 | ✓ | | |
| | Viral vector | ✓ | IM/SC | ✓ | X | | ✓ | | X | Phase 1 | ✓ | | |
| | RNA | X | IV | ✓ | X | | ✓ | | X | Phase 2 | ✓ | | |
| | DNA | ✓ | IM | ✓ | X | | ✓ | | X | Phase 1 | ✓ | | |
| **MERS coronavirus (MERS-CoV)** | Subunit | ✓ | IM | ✓ | ✓ | | ✓ | Epidemic/ pandemic potential | ✓ | Phase 2 | ✓ | Campaign/outreach (similar assumptions as Ebola) | YES |
| | Virus vector (non-replicating) | ✓ | IM | ✓ | ✓ | | ✓ | | X | Phase 1 | ✓ | | |
| **Dengue virus** | Virus vector (replicating) | ✓ | SC | ✓ | ? | Gavi VIS (assessed and deprioritized) | X | Endemic rather than epidemic threat, but geography is expanding | ✓ | PQ/ EUL or licensed | ✓ | Adolescents/ adults (prescreening for seropositivity required) | NO |
| | Nucleic acid (DNA) | ✓ | IM | ✓ | X | | X | | X | Phase 1 | ? | Assume RI of infants is preferred if vaccine safety permits, adolescents/ adults could be targeted | |
| | Subunit | ✓ | IM | ✓ | X | | X | | X | Phase 1 | ? | | |
| | Whole inactivated | ✓ | IM | ✓ | X | | X | | ✓ | Phase 2 | ? | | |
| | Live attenuated | ✓ | SC | ✓ | X | | X | | ✓ | Phase 3 | ? | | |

# Expected complexity of the regulatory pathway - MAPs

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

- Surrogate of efficacy identified/ **low complexity**
- Correlate of Protection or immunological endpoint identified/ **medium complexity**
- No correlate of Protection nor immunological endpoint identified/ **high complexity**

| | Potential vaccine targets for use with MAPs | Expected complexity of the regulatory pathway |
|---|---|---|
| **Legacy** High volumes of vaccines available with low unit price | **Hepatitis B virus** | **Surrogate of efficacy identified** |
| | **Measles and rubella viruses** | **Surrogate of efficacy identified** |
| | **Measles, mumps and rubella** | It is **likely that approval will be possible based on non-inferiority of immune responses** as done with other development efforts on novel delivery systems for MCVs |
| | **Rabies virus** | **Surrogate of efficacy identified** |
| | **Salmonella Typhi** | • Licensure of a TCV MAP should be possible based **on non-inferior immunogenicity** compared with an approved injected TCV<br>• **Data suggest that anti-Vi serum IgA is a Correlate of Protection** against infection and anti-Vi-serum IgG is associated with protection against severe disease |
| | **Yellow Fever** | **Neutralizing antibodies are regarded as a valid Correlate of Protection** |
| **Evolving** Not commoditised/ higher price vaccines, or vaccines still in development | **Group B streptococcus** (GBS), S agalactiae | • **Correlates of Protection are likely to be required** for initial licensure of a GBS vaccine because a pivotal GBS vaccine efficacy trial would require a very large sample size.<br>• **Antibody-mediated risk reduction estimates have been reported** from different studies for anti-capsular antibodies against the most frequent serotypes of GBS.<br>• The **concentration of antibodies required for protection have not been defined.** |
| | **Human papillomavirus** | A **Correlate of Protection for HPV vaccines has not been defined.** Demonstration of **non-inferiority of immune responses is expected to be an acceptable endpoint** for regulatory approvals. |
| | **Neisseria meningitidis A,C,W,Y** | **Correlates of Protection have been defined** for Men A,C,W,Y,X |
| | **Neisseria meningitidis A,C,W,Y,X** | |
| | **Streptococcus pneumoniae** | **Surrogate of efficacy identified.** A non-inferiority threshold of 0.35 µg/mL capsular PS antibody against each serotype is accepted. |
| **Outbreak** Vaccine targets with unpredictable demand driven by outbreaks | **Influenza virus, pandemic and seasonal** | The **CoP for pandemic flu vaccines is assumed to be the same as for seasonal flu** vaccines (surrogate of efficacy) |
| | **SARS-CoV-2** | **Data suggest** serological response to vaccination (measured with Anti-Spike IgG) could be a valid **surrogate of efficacy** |

# Programmatic impact assessments of priority vaccine targets for use with MAPs in LMICs

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

| | Potential vaccine targets for use with MAPs (incl. for LMICs)* | Ability of MAPs to address most important challenges faced by immunisation programmes (from previous country consultations and VIPS assessment ) | Immunisation programmes that could benefit the most from a MAPs presentation (from previous country consultations) | Potential benefits offered by a MAPs (from internal VIPS assessment) | Collected evidence suggesting MAPs offer benefits |
|---|---|---|---|---|---|
| **Legacy** High volumes of vaccines available with low unit price | Hepatitis B virus | ○ (birth dose) | ▲ (birth dose) | ◆ | *Moderate-high* |
| | Measles, mumps and rubella viruses (MR and MMR) | ● (MR) | ▲ (MR) | ◆ | *High* |
| | Rabies virus | ● | ▲ | ◆ | *High* |
| | Salmonella Typhi | ● | △ | ◇ | *Low* |
| | Yellow Fever | ● | ▲ | ◆ | *High* |
| **Evolving** Not commoditised/ higher price vaccines, or vaccines still in development | Group B streptococcus (GBS), S agalactiae | N/A | N/A | ◆ | *Moderate* |
| | Human papillomavirus | ● | ▲ | ◆ | *High* |
| | Neisseria meningitidis A,C,W,Y (X) | ● (Men A) | ▲ (Men A) | ◆ | *Moderate* |
| | Streptococcus pneumoniae | N/A | N/A | ◇ | *Low* |
| **Outbreak** Vaccine targets with unpredictable demand driven by outbreaks | Influenza virus, seasonal and pandemic | N/A | △ | ◆ | *Moderate* |
| | SARS-CoV-2 | N/A | N/A | ◆ | *Moderate* |

| | | |
|---|---|---|
| ○ 1-2 top 5 immunisation challenges addressed by MAPs | ● 3 top 5 immunisation challenges addressed by MAPs | ● 4-5 top 5 immunisation challenges addressed by MAPs |
| △ Ranked amongst top 9-11 vaccines that could benefit from MAPs | ▲ Ranked amongst top 5-8 vaccines that could benefit from MAPs | ▲ Ranked amongst top 4 vaccines that could benefit from MAPs |
| ◇ 0-2 potential benefits offered by a MAPs | ◆ 2-3 potential benefits offered by a MAPs | ◆ 4-5 potential benefits offered by a MAPs |

# Financial sustainability/ funders interest assessments of priority vaccine targets for use with in LMICs - MAPs

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

| | **Potential vaccine targets for use with MAPs** (incl. for LMICs)* | **Potential dual market (HIC on top of LMIC market)** | **Known funder, MD or VM interest in vaccine-MAP** | **Clinical trial stage** (most advanced vaccine for each target) | **Financial sustainability/ funders interest** |
|---|---|---|---|---|---|
| **Legacy** High volumes of vaccines available with low unit price | Hepatitis B virus | **Yes** | **Yes** | Clinical (adults) | *High* |
| | Measles, mumps and rubella viruses | **No** (MR), **Yes** (MMR) | **Yes** (MR), **No** (MMR) | Clinical (MR) | *Medium* |
| | Rabies virus | **Maybe** (travellers and high-risk occupations) | **Yes** | Preclinical | *Medium-high* |
| | Salmonella Typhi | **Maybe** (travellers and military) | **Yes** | Concept | *Medium-high* |
| | Yellow Fever | **Maybe** (travellers) | **No** | Concept | *Medium-low* |
| **Evolving** Not commoditized/higher price vaccines, or vaccines still in development | Group B streptococcus (GBS), S agalactiae | **Yes** | **No** | Concept | *Medium* |
| | Human papillomavirus | **Yes** | **Yes** | Preclinical | *High* |
| | Neisseria meningitidis A,C,W,Y,X | **Maybe** (serotype X is less of a problem in HICs) | **No** | Concept | *Medium-low* |
| | Streptococcus pneumoniae | **Yes** | **No** | Preclinical | *Medium* |
| **Outbreak** Vaccine targets with unpredictable demand driven by outbreaks | Influenza virus, pandemic | **Yes** | **Yes** | Clinical (seasonal) | *High* |
| | SARS-CoV-2 | **Yes** | **Yes** | Clinical | *High* |

# Assessment of the CTC shortlist on potential programmatic impact of CTC use

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

| CTC SHORTLIST | Potential Programmatic impact | Qualitative rationale for assessment | |
|---|---|---|---|
| | | Use case for CTC | Priority during consultations* |
| Hep B (birth dose) | **HIGH:** CLEAR USE CASE/ NEED IDENTIFIED FOR CTC | • Outreach within **24 hrs of home births**, often in **remote areas** | High |
| MR- MAP | | • Measles campaigns are common and frequent across many countries, and **outbreaks are increasing** in the post-COVID-19 era. Use in campaigns/ outbreaks as a MAP product. | High |
| SARS-COV-2 | | • **Mass immunization campaigns** | High |
| HPV | | • Mixed outreach interventions to **schools, health facilities and community** | Med - High |
| OCV | | • Cholera hotspots are often **inaccessible** or in **conflict** areas, where CTC use could help **improve access.** Rapid response during **emergency outbreaks** which is less feasible when cold chain adherence is required | Med- High |
| TCV | **MED** CURRENT NEED OR MAY MOVE INTO ROUTINE USE IN THE FUTURE | • Initial use in **campaigns** and possibility to **integrate with HPV** given the same age cohort | Med |
| dT (adults/ adolescents) | | • School based vaccinations could be **co-delivered with CTC qualified HPV** potentially reducing cold chain requirements | Med |
| Meningitis A,C, W, Y (X) | | • The Meningitis belt goes right across the bottom of the Sahara desert and includes both the **world's poorest and hottest countries**, making CTC a compelling option. Initial use in campaigns followed by routine use in the future. | Med |
| Rabies | **LOW**: UNCLEAR USE CASE/ NEED OR CTC WOULD BRING ADDITIONAL COMPLEXITY | • Access issues for remote target population in **hard-to-reach areas**; requires **emergency response** for post-exposure prophylaxis. Often delivered outside of EPI, where cold chain management is less stringent. | Low |
| Dengue | | • Currently prequalified product needs **pre-vaccination serological screening** (CYD-TDV); may not be needed for the new vaccine | Low |
| M. TB – BCG | | • Vaccination of infants including home-births, often in **remote areas;** but **lower urgency** than Hep-B birth dose | Med |
| Hep B (adults) | | • Often delivered outside of EPI, where cold chain management is less stringent.<br>• HepB adult vaccination for a limited population (only at-risk adults) **may be facility-based** in many cases, reducing the need and benefit of CTC | Low |

**Two consultations have been conducted on CTC – one country consultation and another with programmatic experts; both with very small n-sizes and used for directional insights only. Previous VIPS country consultations also focused on heat stable vaccines/CTC.*

# Assessment of the CTC shortlist based on considerations of commercial feasibility

VIPS VACCINE INNOVATION PRIORITISATION STRATEGY

| CTC SHORTLIST | Potential commercial feasibility | Qualitative rationale for assessment | | |
|---|---|---|---|---|
| | | Existing vaccine funded / prioritised by Gavi or CEPI*? | LMIC market? | Manufacturer interest in CTC qualification as a proxy/ first step to CTC |
| Human papillomavirus (HPV) | **HIGH**: CTC QUALIFIED PRODUCT ALREADY EXISTS OR POTENTIAL INTEREST | **Yes** – Gavi funded | **Yes** | **CTC qualified product** on the market |
| Oral Cholera Vaccines (OCV) | | **Yes** – Gavi funded & VIS, CEPI priority | **Yes** | **CTC qualified product** on the market |
| Typhoid conjugate vaccine (TCV) | | **Yes** – Gavi funded | **Yes** | **CTC qualified product** on the market |
| Meningitis A,C, W, Y (X) | | **Yes** – Gavi VIS | **Yes** | **Potential interest** |
| Hepatitis B (birth dose) | **MED**: NO PRODUCT ON MARKET BUT COULD CHANGE IF SUPPORT/ INCENTIVES IN PLACE | **Yes –** Learning agenda for Gavi VIS; CEPI List of Pathogens for thermostability improvements* | **Yes** | May need additional support – financial/ regulatory |
| Measles-Rubella (MR)-MAP | | MR is Gavi funded<br>MR-MAP funding & development uncertain | **Yes** | CTC is part of the preferred attributes of the MR-MAP TPP |
| dT (reduced d antigen for adults/adolescents) | | **Yes –** Gavi VIS for D,T & P containing boosters | **Yes** | May need additional support – financial/ regulatory/ other |
| SARS-COV-2 | | **Yes** – Gavi funded | **Yes** | **Likely limited interest** |
| Rabies | **LOW: LIKELY** NO COMMERCIAL INTEREST IN CTC DEVELOPMENT OR BUSINESS CASE | **Yes** – Gavi VIS & CEPI List of Pathogens for thermostability improvements* | **Yes** | **No known interest** |
| Dengue | | **No** | **Small** | **No known interest** |
| Hep B adults | | **No** | **Small** | **No known interest** |
| M.TB - BCG | | **No** | **Yes** | **No known interest** |

*https://cepi.net/wp-content/uploads/2022/01/CfP-thermostability_Jan2022_CallText.pdf