



How, where and when are we going to use microarray patches to deliver measles and rubella vaccines?

Mateusz Hasso-Agopsowicz (WHO)



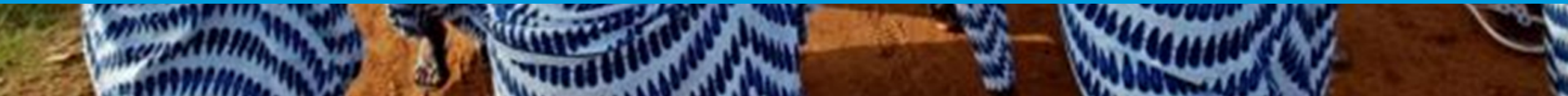
16th TechNet Conference
Shaping a resilient and adaptive immunization program

How, where and when are we going to use microarray patches to deliver measles and rubella vaccines?

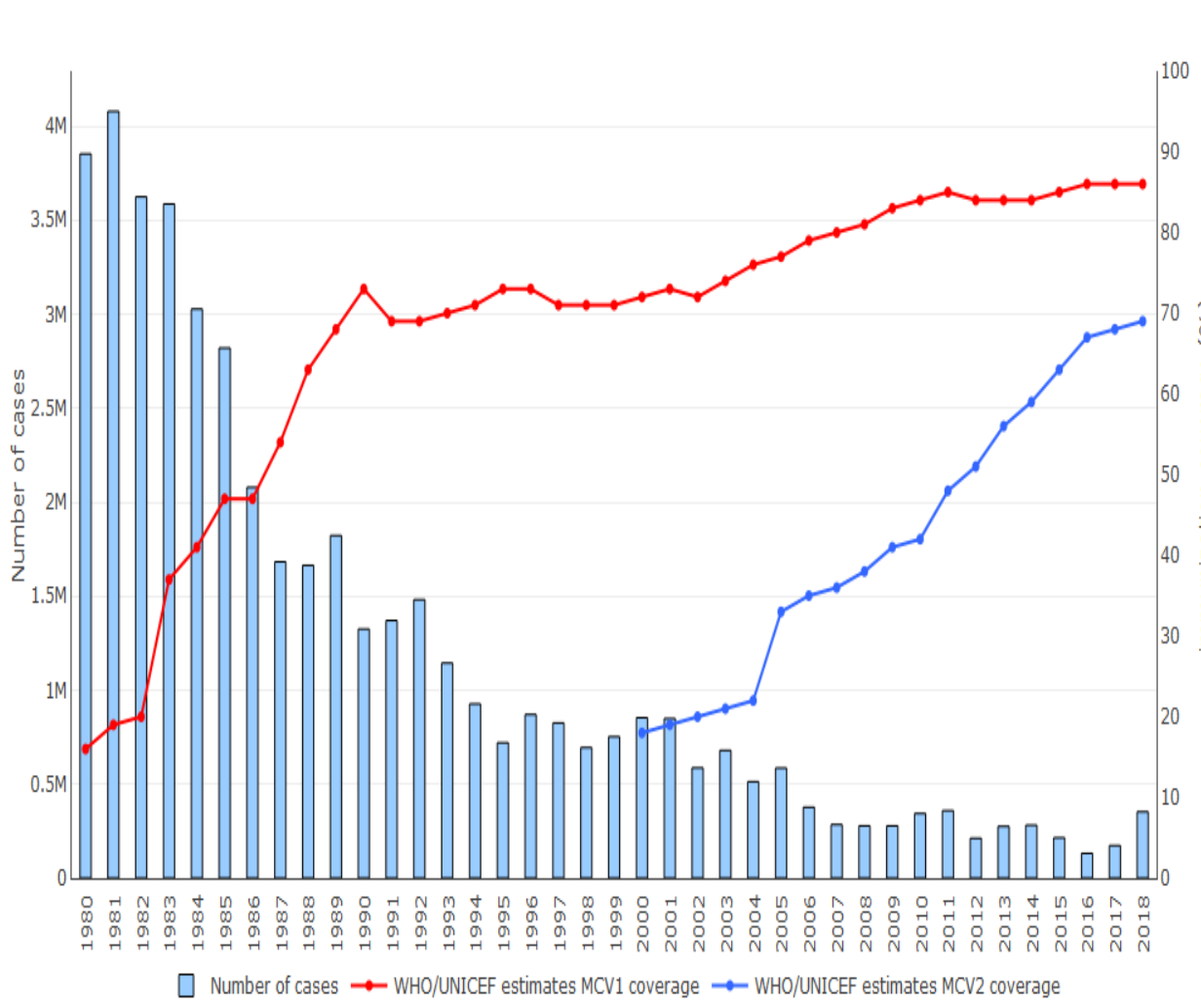


Mateusz Hasso-Agopsowicz (WHO), Birgitte Giersing (WHO)

MMGH Consulting



Global reported Measles cases and MCV1 and MCV2 coverage, 1980-2019



Challenges with the current needle and syringe MCV delivery:



- Safety of reconstitution and administration
- Stringent cold chain requirements
- Complex handling, time for administration and availability of trained health care workers
- Vaccine hesitancy & wastage
- Medical waste disposal

Potential public health benefits of vaccine-MAPs

Microarray patches (MAPs) consist of hundreds or thousands of tiny projections that deliver dry vaccine just below the skin surface, with some MAPs applied like a bandage and others requiring an applicator for delivery.

- Increased **ease-of-use**; avoids reconstitution and requires less preparation
- Fewer components, **simplifying** supply chain logistics.
- **Increased acceptability** by caregivers and vaccinees.
- **Sharps-free**, which improves safety.
- Potential to save **health care worker time** by eliminating the need for reconstitution.
- Potential for **enhanced heat stability** and **freeze resistance**
- **Broad applicability** to all/most parenteral vaccines and might facilitate novel vaccine combination.
- MAP delivery may **enhance immunogenicity** so that fewer doses and/or less antigen per dose may be required



Recommendation by SAGE, October 2016

Outcomes from WHO MCV-MAP meeting



.....SAGE recommended that the **most expeditious clinical development and regulatory pathway to licensure of measles containing vaccines (MCV) micro-array patch (MAP) be determined, and that barriers to the development, licensure, and use of MAPs for measles and rubella vaccine delivery be identified and addressed urgently.**



Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

2 DECEMBER 2016, 91th YEAR / 2 DÉCEMBRE 2016, 91^e ANNÉE
No. 48, 2016, 91, 561-584
<http://www.who.int/wer>

MR-MAP Key Challenges

Understand the product

What are the key product attributes of MR-MAPs to make an impact in LMICs?

How: Use case

How will MR-MAPs be used when introduced to country immunisation programmes?

Where: Market

What will be the demand for each of the use cases (sizing)? How will that determine the importance of product attributes?

When: Development pathway and licensure

What are the additional activities that we need to undertake to prioritise MR-MAP development?

What are WHO and partners doing to advance MAPs?



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HOW will the MR-MAPs be used in countries: development of MR-MAPs use cases

Use Case is a specific situation in which a product or a service could potentially be used to accomplish a defined goal

Use Cases are used for:



PRODUCT DESIGN

What are the most appropriate product features to address the subjects emerging and unmet needs?



PROGRAMME DESIGN

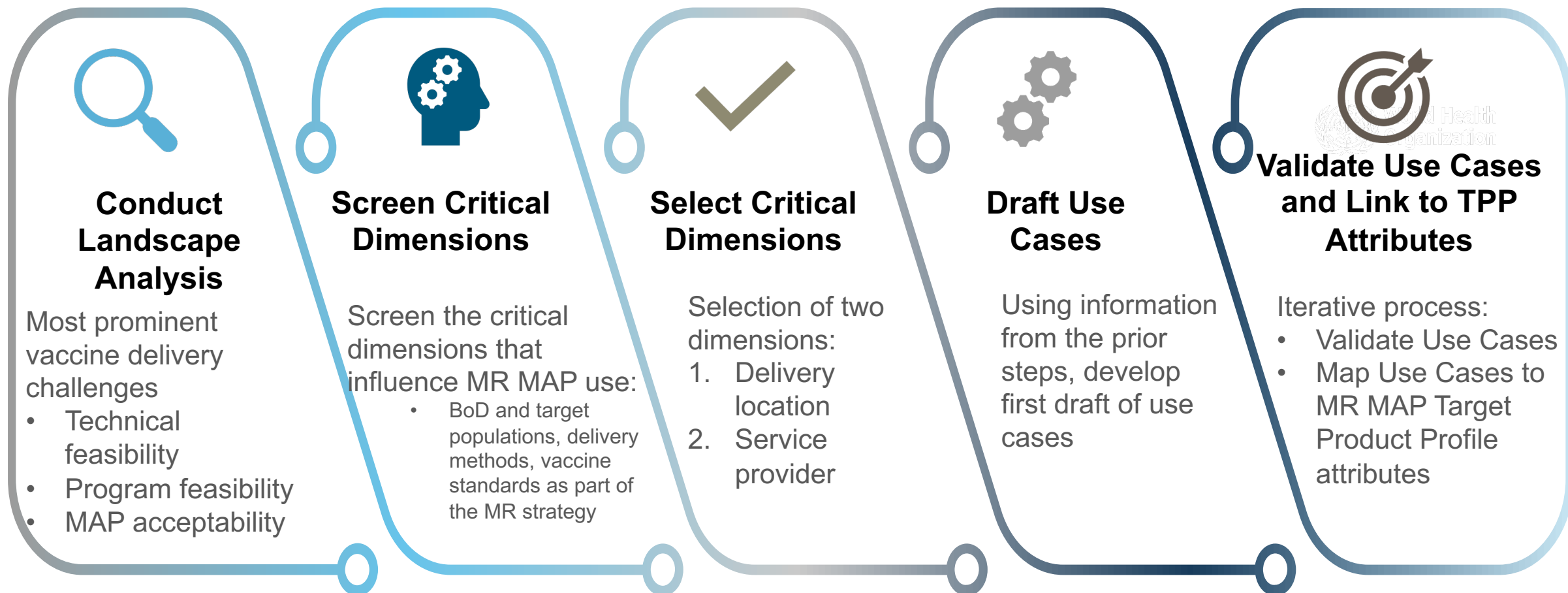
How should the program be designed to maximize its reach and efficiency?



SUCCESS FACTORS

What product or program features contribute to the success or failure of the intervention?

How were the MR MAP Use Cases developed?



Use cases identified for MR-MAPs



Fixed Health Post
(full cold chain capabilities)



1 Delivery by HW or CHW in Fixed Post
Fixed health post is defined as a permanent structure which has full cold chain capabilities

Outreach (reduced cold chain capabilities)



2 Outreach delivery by HW
Includes delivery in areas that do not have access to a fixed health post conducted by health workers and with reduced or no cold chain capacities.

3 Outreach delivery by CHW
Includes delivery in areas that do not have access to a fixed health post conducted by community health workers and with reduced cold chain capacities.

Other settings
(no cold chain)



4 Delivery by CHW in their "home" community
The CHW residing in a specific area is given a stock of MR-MAPs and can deliver them within their own community as needed.

5 Self-administration with HW or CHW assistance
The MR-MAP is self-administered by the individual with the assistance or under supervision of HW or CHW, who is able to monitor for AEFI and record and report who has received the vaccination.

6 Self-administration without assistance²
The MR-MAP is self-administered by the individual. The vaccination would be monitored and supervised by another individual who has received minimal training

1. Community health worker provide health education, referral and follow-up, case management and basic preventive health care and home visiting services to specific communities. They provide support and assistance to individuals and families in navigating the health and social services system. Occupations included in this category normally require formal or informal training and supervision recognized by the health and social services authorities
2. This may include community member assistance, (e.g., teachers, elders, etc.) who have not been training in MAPs but can monitor and document the administration

Validation of use cases through surveys and interviews



SURVEYS

Broad consultation to obtain general perceptions of the Use Cases as well as input and feedback to refine their definitions or identify new Use Cases



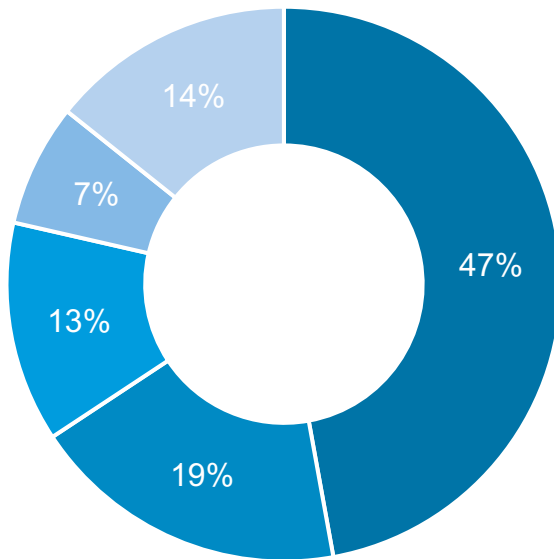
INTERVIEWS

Deep dives into the country perspectives for how the MR MAPs could be used and where they would be most beneficial

Survey Demographics – Organization Type, Role and Region

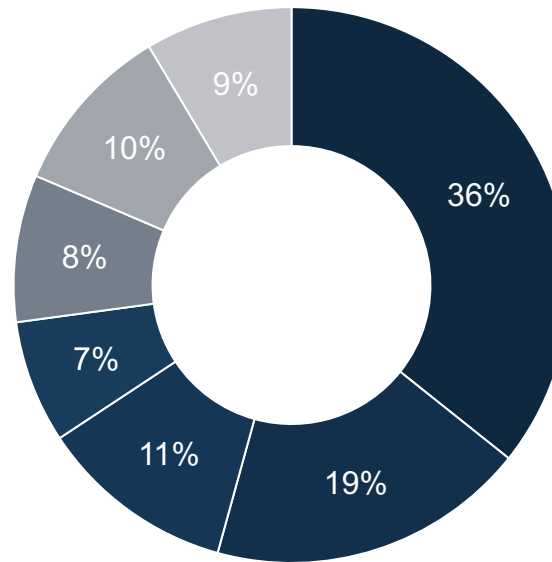
Total number of respondents: 70

Type of organisation



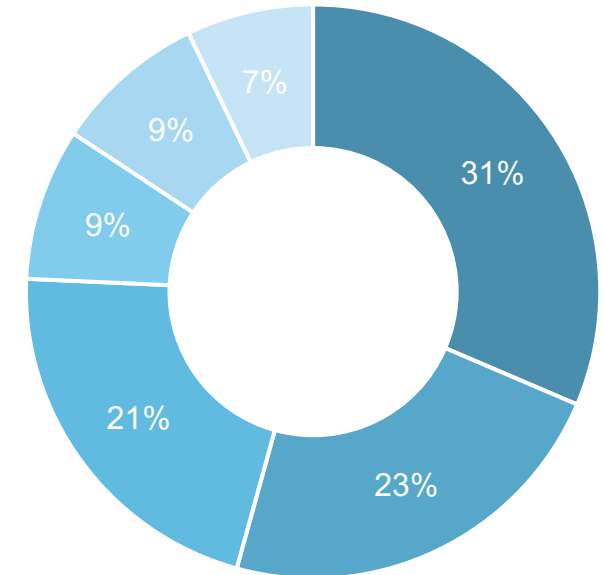
- Agency of the United Nations
- Industry / Product Development / Design
- Implementation but not gov't or UN
- Ministry of Health
- Other

Current role



- Immunisation
- Researcher
- Surveillance
- Other
- Epidemiologist
- EPI manager
- Develop / Manuf

Region

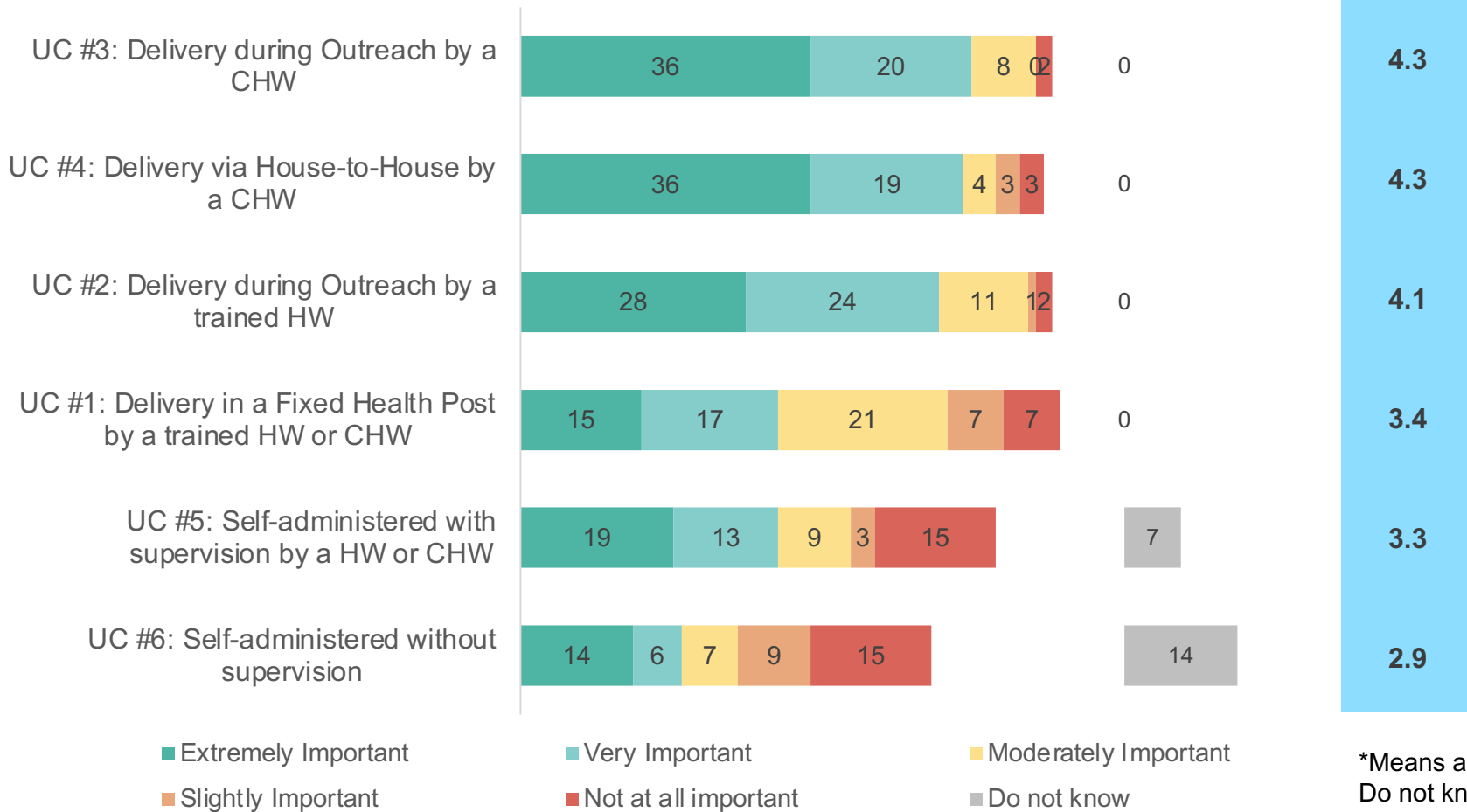


- AMRO
- AFRO
- EURO
- SEARO
- EMRO
- WPRO

Survey Results : Importance of the defined use cases

Total number of respondents: 70

Q11: Importance of MAPs to achieve MR goals (N)



Key findings from the survey

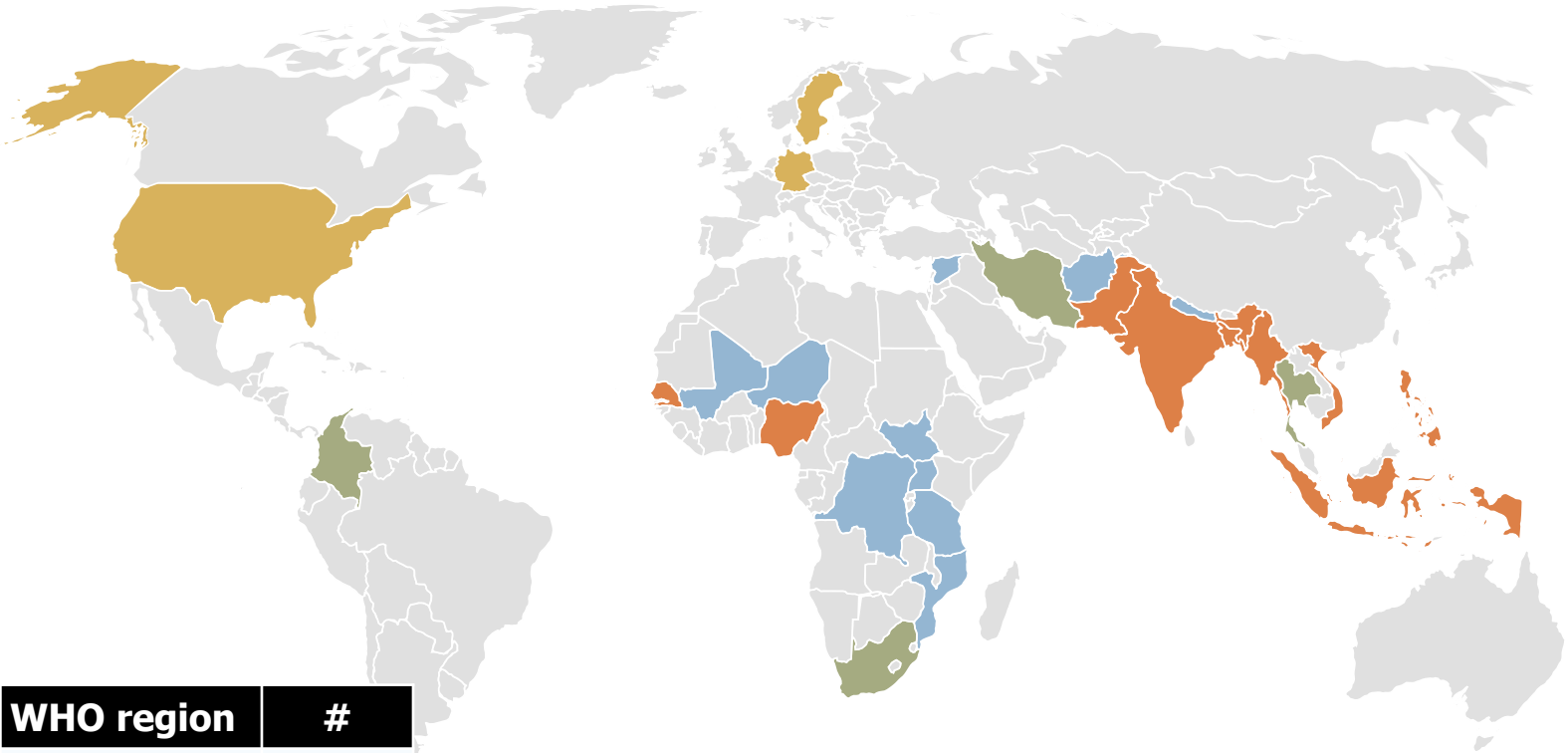


- General agreement on MAP use cases using outreach and house-to-house delivery (UC2 to UC4)
- Discordant opinions on use cases with self-administration (UC5, UC6) and fixed health posts delivery (UC1) as well as which countries (by income group) may use MAPs



- More feedback from government representatives or individuals working in countries obtained from interviews
- This included exploration regarding self-administration and fixed health post use

Interview demographics



WHO region	#
AFRO	12
AMRO	3
EMRO	5
EURO	2
SEARO	5
WPRO	3

WB income group [†]	#
High income	3
Upper middle income	4
Lower middle income	10
Low income	11

- Low income
- Lower middle income
- Upper middle income
- High income

- 30 individuals were interviewed across the World Bank Income Group Classifications
- 2 WHO regional reps
- 26 countries*
- Interviewees comprised of 16 EPI managers and 14 WHO immunization focal points at the country or regional level

*Two individuals were interviewed for both Tanzania and Nigeria
Two individuals represented regional offices

Key emerging themes from interviews

UC3 and UC4 had the highest level of interest

- Country specific context and goals affect how MR MAPs will be used, but most felt UC1-4 were possible with UC3 & UC4 being the most interesting
- Respondents felt that MAPs will largely help to reach remote, border, or security compromised areas as well as pockets of susceptible and vulnerable populations (migrants, slums areas)

MMR/MMRV countries also expressed interest in using MAPs

- HICs and others with MMR / MMRV in routine schedules are interested in using MR MAPs in specific settings
- Some were open to using MR MAPs for traveler vaccination, hesitant populations demanding low-valent vaccines, asylum seekers or other marginalized groups

More acceptance of UC5 and UC6

- UC5 and UC6 are more nuanced and respondents saw opportunities, especially for UC5 in times of COVID-19 (DRC, Mozambique, Indonesia)
- Barriers of legal constraints, monitoring & reporting must be addressed if UC5 and UC6 will be used

All respondents felt MR MAPs will be a positive innovation

- There is a lot of interest and anticipation for MR MAPs. All interviewees viewed MR MAPs as a positive innovation that could help them achieve their MR related goals and many asked for further information

Where will MR-MAPs be used: MR-MAP use case sizing exercise

? WHY?

Aims to capture the **potential use** (number of doses) of MR-MAPs **per use case** for strategic and directional discussions with stakeholders, including manufacturers / developers and potential users / purchasers

HOW?

- Leveraging MCV demand forecast estimates
- WHO Global Health Workforce Statistics, World Bank Database, cMYP, JRF, ...
- Interviews to identify country and regional specific assumption and data
- Consultations to consolidate and agree on data inputs and assumptions

If you would like to participate please email hassoagopsowicz@who.int

When: VIPS is now creating 5-year action plans to advance the prioritised innovations



Assessment and landscaping:

- Key challenges, bottlenecks and needs related to product innovations' development and uptake
- Existing initiatives
- Gaps

Defining end-to-end strategies to accelerate development and uptake:

- Priority activities for the next 5 years – per innovation and cross-cutting
- Roles and responsibilities
- Funding
- Timelines

Interviews with
manufacturers,
developers and
implementation
partners

Joint VIPS Alliance
action plan

VIPS partners are best placed to undertake these activities and will assess what each organisation can deliver and potentially engage beyond VIPS partners to ensure appropriate resources.

Adapted from VIPS slides

Summary

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Achievements and Remaining work

Publication of MR-MAP Target Product Profile (TPP) in June 2019

Development of six use cases to deliver MR-MAPs

Ongoing work to understand the potential size of each of the use cases

MAPs prioritised as novel technology devices through Vaccine Innovation Prioritisation Strategy, action plans developed with related workstreams

Thank you



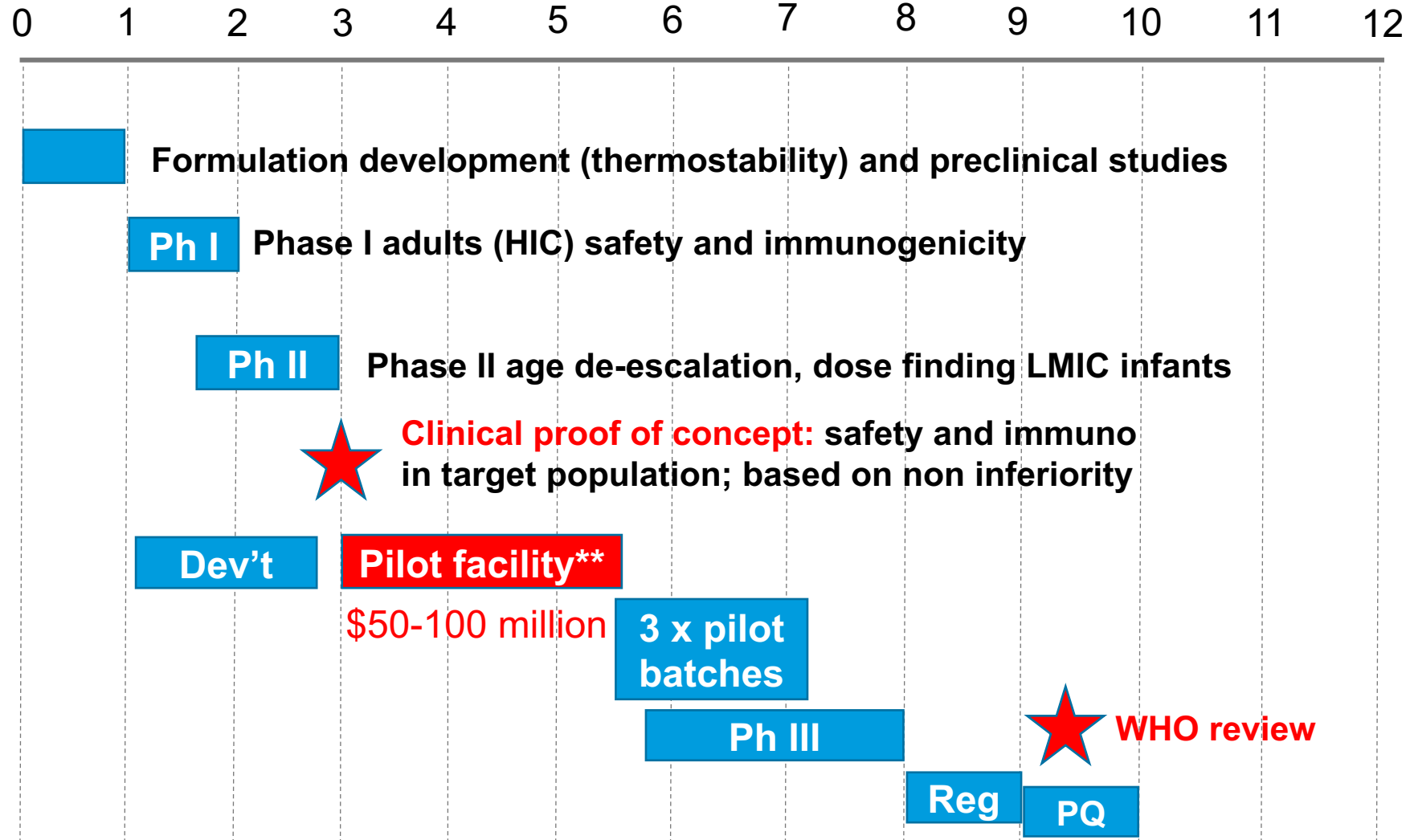
World Health
Organization

WHO

20, Avenue Appia
1211 Geneva

Switzerland

Investment in MAP pilot facility has been a major bottleneck for MCV-MAP



MR-MAPs have not yet entered Phase 1 clinical studies



The value proposition and **business case is poorly understood** for MAP developers

Need to **understand market demand** before major investments take place

** could be longer if building not available and agreements not in place

Overview of MR MAPs use case sizing approach (1/2)

