WHO Preferred Product Characteristics for Malaria Vaccines:

Bridging Vaccine R&D with Public Health

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Purpose of this SAGE session

- 1) For information: SAGE to be informed about the update to the malaria vaccine technology roadmap, including new Vision & Strategic Goals
- 2) Input into plans for WHO Preferred Product Characteristics for malaria vaccines

Malaria Vaccine Technology Roadmap: Original 2006 Vision

Vision

The malaria vaccine community will develop an effective vaccine that prevents severe disease and death caused by *Plasmodium falciparum* malaria in children under five in sub-Saharan Africa and other highly endemic regions. Efficient global coordination and collaboration will stimulate the malaria vaccine pipeline and accelerate progress towards this achievement.

Malaria Vaccine Technology Roadmap: Original 2006 Strategic Goal

Strategic Goal

By 2025, develop and license a malaria vaccine that has a protective efficacy of more than 80% against clinical disease[1] and lasts longer than four years.

Process for Roadmap update

- First public consultation in September 2012 – 45 written submissions from agencies and vaccine development groups
- Second public consultation in November 2012 – few comments.
- WHO Meeting on 5 February 2013 with 40 participants
- Vision and Strategic Goals to be finalized on April 24 at meeting of funding agencies and WHO

Updated Vision

- Safe and effective vaccines against *Plasmodium falciparum* and *Plasmodium vivax* that prevent transmission, disease and death to enable malaria eradication.

Updated Strategic Goals

- By 2030, license vaccines targeting *Plasmodium falciparum* and *Plasmodium vivax* and encompassing the following two goals, for use by the international public health community:
  - *Malaria vaccines with a protective efficacy of at least 70-80% against clinical malaria, suitable for administration to appropriate at-risk groups in malaria-endemic areas.*
  - *Malaria vaccines that reduce transmission of the parasite and thereby substantially reduce the incidence of human malaria infection. This will enable elimination in multiple settings.*

New Strategic Goals: vaccines to prevent clinical malaria and achieve elimination

- Goals focus on desired outcomes of vaccination
- Product development pathway differs by desired outcome, and by antigenic target
- Substantial further guidance needed to define efficacy criterion and product development pathway for malaria elimination vaccines

Development of WHO Preferred Product Characteristics

- The two strategic goals above provide guidance on the highest priorities in terms of public health need for malaria vaccines.
- Two sets of WHO preferred product characteristics (PPCs) will be developed in 2013-2014
- These PPC will provide technical guidance on the desired characteristics of malaria vaccines to meet the strategic goals
- “What we want to see developed to achieve priority public health goals.”

Preferred Product Characteristics: What they are & what they are not

What they are

- Guidance from WHO for vaccine developers to take into account when designing vaccines and trials at early stage of vaccine R&D
- Will need to change in line with the scientific state-of-the-art and needs of country programmes (with ongoing review process)

What they are not

- They are not static exit criteria. Innovation is encouraged and harnessed to meet public health needs
- They do not replace standard policy or PQ processes

Outline workplan for development of WHO PPCs

- Ongoing consultation with funders group representatives, vaccine developers and WHO advisory committees
- Aim: Ensure common understanding of intended purposes, and agree use for PPCs.
- Primary audience for PPCs is vaccine developers and product development focused agencies

	Morbidity	Transmission/Elimination
Indication	+	++
Target Population	++	+++
Dosage	+ (PSPQ)	+ (PSPQ)
Route of Immunization	+	+
Presentation	+ (PSPQ)	+ (PSPQ)
Storage	+ (PSPQ)	+ (PSPQ)
Safety	+	+
Efficacy	+	+++
Lack of interference	+	+
Packaging	+ (PSPQ)	+ (PSPQ)
Registration/PQ	+	+

+++ indicates most activity needed to provide guidance

Outline workplan for development of WHO PPCs

- Efficacy & target age groups for transmission/elimination PPC:
  - Q3-4 2013 Multidisciplinary consultation involving modellers, biologists, statisticians, epidemiologists, clinical trialists, representatives from regulatory and malaria endemic country authorities.
  - Include summaries of existing work from other agencies
  - Consider whether different criteria will be essential for different transmission settings
  - Include guidance on surrogate endpoints that may accelerate timelines

Outline workplan for development of WHO PPCs

- Programmatic Suitability:
  - Review existing WHO Programmatic Suitability for Prequalification document and include criteria, with changes only if necessary.
  - Consultation with relevant WHO advisory groups on specific criteria for malaria vaccines (eg IPAC, VPPAG)
  - Ensure complementary to existing guidance
  - Communicating existing guidance to vaccine R&D community will be valuable

Criteria for transmission/elimination PPC (Indicative wording to stimulate discussion)

1. Indication: Prevention of transmission of P. falciparum and/or P. vivax (according to epidemiological setting)

2. Target Population: Total population in malaria-endemic setting

3. Dosage: Preferably one immunization. Minimally three in primary series. Preferably one dosage level regardless of age.

Criteria for transmission/elimination PPC 2

4. Route of Immunization: Any route implementable on a large scale without the need for extensive health provider's training

5. Presentation: >=10 doses per vial; preferably liquid

6. Storage: Shelf-life at least 2 years. Preferably ambient, minimally 2-8°C. A vaccine vial monitor should be attached.

7. Safety: Preferably superior to that of currently licensed paediatric vaccines. Minimally non-inferior

Criteria for transmission/elimination PPC 3

8. Efficacy: ??? To be developed, including endpoints, trial design

9. Interference: No significant interference with other vaccines planned for co-administration

10. Packaging: A smaller packed volume is preferred

11. Product registration and prequalification: The product must be WHO pre-qualified

Conclusion

- Updated Malaria Vaccine Technology Roadmap to be launched during 2013:
  - Please assist with communication to vaccine R&D agencies
- We seek input from SAGE into plan for development of WHO Preferred Product Characteristics (PPC) for malaria vaccines
- Malaria PPC aimed for finalization by end 2014