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 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
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
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+++ 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

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
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