Updating the Malaria Vaccine Technology Roadmap

Vasee Moorthy MRCP PhD

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Purpose of this MPAC session

- MPAC to be updated on the strategic R&D framework for malaria vaccines, including new Vision & Strategic Goals
- Input into plans for WHO Preferred Product Characteristics
- Process for agreement of efficacy criterion for elimination vaccines is a challenging element
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.

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 update

- Public consultation process for updates to Vision and Strategic Goal
- Agreement on final wording between WHO and Malaria Vaccine Funders Group.
- Development of Preferred Product Characteristics for the new Strategic Goals to follow the Update. This will be a WHO process.
Process for update

- First public consultation in September 2012 – 45 written comments from agencies and vaccine development groups
- Second public consultation in November 2012 – few comments. Timeframe and efficacy threshold main discussion points.
- WHO Meeting on 5 February 2013 with 40 participants, including five MPAC members
- To be finalized on April 24 at meeting of funding agencies
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.
Safe and effective vaccines against *Plasmodium falciparum* and *Plasmodium vivax* that prevent transmission, disease and death to enable malaria eradication.
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.
By 2030, license vaccines targeting *Plasmodium falciparum* and *Plasmodium vivax* and encompassing the following two objectives, for use by the international public health community:
Updated Strategic Goal on vaccines to prevent clinical malaria

- POST FEB 5: 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.
New Strategic Goal 2: vaccines to reduce transmission & achieve elimination

- Malaria vaccines that inhibit transmission of the parasite and thereby substantially reduce the incidence of human malaria infection to achieve elimination in multiple settings. The vaccines should be suitable for administration to people of all ages in mass campaigns.

- Key message: Goals focus on desired outcomes of vaccination, not the antigenic target of the vaccine.

- Product development pathway differ by desired outcome, and by antigenic target.
The strategic goals above provide guidance on high 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 about the desired characteristics of malaria vaccines to meet the strategic goals.

What we want to see developed to achieve priority public health goals. Should enable and guide product development, not restrict it.
Outline workplan for development of WHO PPCs

- Consult with funders group representatives, vaccine developers and WHO advisory committees

- Aim: Ensure common understanding of intended purposes, and agree use for PPCs.

- Use will differ for different agencies. Primary audience is vaccine developers and product development focused agencies
Purpose of WHO Preferred Product Characteristics (PPC) for Malaria Vaccines

- Guidance on key performance characteristics (safety, efficacy) for new malaria vaccines
- Guidance on key target groups
- Guidance on minimum programmatic suitability criteria to enable delivery of vaccines once available.
- Support strategic discussions on vaccine development
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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
  - Include MPAC input
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
- Keep this light, as guidance already available
Criteria for transmission/elimination PPC (WHO 2003 draft document as starting point)

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 or two immunizations, maximum of three immunizations. Preferably one dosage level regardless of age.
5. Route of Immunization: Any route implementable on a large scale without the need for extensive health provider’s training

6. Presentation: Large multidose vials; preferably liquid

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

8. Safety: Preferably superior to that of currently licensed paediatric vaccines. Minimally non-inferior
9. Efficacy: ???

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

11. Packaging: Ensure minimal storage requirements

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

- Updated Roadmap to be launched during 2013:
  - Please assist with communication to vaccine R&D agencies

- Input from MPAC into plan for development of WHO Preferred Product Characteristics
  - Delegate 1-3 members to working group, to join 1-3 members from SAGE?
  - Provide feedback on certain aspects that must be taken into account

- To be discussed at SAGE in April, and PPCs in other disease areas may follow