Update on the RSV Vaccine Technology Roadmap
2015 PD-VAC meeting

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Purpose of the R&D Roadmap for RSV Vaccine Development

Capture in a single WHO document:

• Agreed strategic goals: ie unmet public health needs to be met by vaccination

• Critical Research, Product Development and Capacity issues, which if addressed in a systematic manner will improve the quality and timeliness of data available for decision-making
Vision

High-quality, safe and effective RSV vaccines that prevent severe disease and death in infants less than 12 months old and reduce morbidity in children less than 5 years old.
Strategic goals

- Maternal/passive immunization to prevent severe RSV disease in infants

- Active paediatric immunization to prevent RSV disease in infants and young children beyond the period of passive protection afforded by maternal immunization
Roadmap priority areas

- Epidemiology/modelling
- Preclinical models & assays
- Product development
- Key capacities
- Communication/advocacy
Epidemiology/modelling

Key points

- Generate improved estimates of age-stratified disease burden and mortality in infants, particularly in LMICs

- Improve global characterization of RSV seasonality in representative settings

- Design surveillance and vaccine efficacy studies to allow collection of data on the long term effects of RSV vaccination on wheezing illness and reactive airway disease
Preclinical models & Assays

- Develop common, purified challenge virus strains to improve the quality and aid comparability of results between laboratories

- Develop an international reference serum standard to facilitate comparison across MNT, PRNT and reporter virus assays

- Establish a repository for microneutralization, PRNT and reporter virus assay protocols to enable access and encourage harmonization of assays for vaccine developers

- Establish consensus regarding the strategy for preclinical evaluation and prioritization of vaccine candidates
Product development

Key points

- Develop PPCs to define WHO’s preferences for RSV vaccine parameters in line with strategic goals.
- Establish case definitions for RSV disease in infants and young children, in high-, middle-, and low-income country target populations.
- Standardize key elements of vaccine clinical trial design, including clinical endpoints, and clarify RSV vaccine regulatory approval pathways for vaccines for maternal and infant immunization in high-, middle-, and low-income country target populations.
- Develop immunological correlates of vaccine induced protection.
Key Capacities

- Establish manufacturing capacity to support global RSV cGMP manufacture for late stage clinical testing and commercial production
- Establish GCP capacity and preparedness for RSV vaccine trials at sites chosen to be representative in Latin America, Africa and Asia.
- Support regulatory capacity strengthening for clinical trial authorisation, and consideration of licensure submissions through existing regulatory networks such as AVAREF and DCVRN
Communication/advocacy

- Develop educational tools and clear messages related to RSV disease burden and potential benefits of vaccination for patients, clinicians, and policy makers
- Identify lessons learned from other maternal immunization programmes, including tetanus and influenza to guide communication about future RSV vaccines for vaccination of pregnant women
- Collaborate with other maternal vaccination efforts (influenza, GBS) to proactively develop strategies to educate and mitigate the liability associated with vaccination during pregnancy.
Next steps

- Finalise draft with the RSV the Working Group – ongoing

- Finalise with PD-VAC committee, and a group of key funding stakeholders

- Disseminate for public consultation through WHO website posting – available online by year end

- Present at global RSV vaccine meeting in 2016
RSV Technology Roadmap WG members

- Ruth Karron
- Barney Graham
- David Kaslow
- Peter Smith
- Narendra Arora