WHO Agenda on Maternal Immunization – an update

Joachim Hombach
Initiative for Vaccine Research

Geneva
16 April 2015
WHO's Seasonal Influenza Vaccine Recommendations

### 2012
- **WHO position paper**
  - Prioritization of pregnant women

### 2013
- **Strategic Advisory Group of Experts (SAGE)**
  - WHO to plan maternal immunization agenda
- **Global Advisory Committee on Vaccine Safety (GACVS)**
  - Inactivated vaccines safe in pregnant women and offspring

### 2014
- **WHO Maternal Influenza Immunization Project**
  - Support adoption of maternal immunization in countries
  - Address uncertainties related to evidence, regulation, implementation and supply
Countries with Influenza Vaccination Recommended in the National Immunization Programme, 2015

Data source: WHO/IVB Database, as of 05 March 2015

Map production Immunization Vaccines and Biologicals (IVB), World Health Organization

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement. ©WHO 2015. All rights reserved.

- Introduced* to date (78 countries or 40%)
- Introduced* in parts of the country (2 countries or 1%)
- Not Available, Not Introduced/No Plans (114 countries or 59%)
- Not applicable

* Includes partial introduction
Maternal Influenza Immunization:

Main objectives

Strengthen the evidence base on maternal influenza immunization supporting country decision-making and investment decisions

Address obstacles to implementation of maternal immunization (influenza and other vaccines)
Maternal Influenza Immunization at IVR: Areas of work

- IVR Policy Development and Optimization (PDO) Team
- Numerous activities involving multiple WHO departments and collaboration with several partner institutions
- Designed to address data gaps and implementation obstacles to maternal influenza immunization program implementation

- Burden of Disease
- Vaccine Safety
- Vaccine performance
- Impact and Economics
- Data Review and Synthesis
- Tools for Country Decision-Making
- Programme Implementation
- Regulatory
- Supply & Manufacturing
Collaborative efforts within WHO: Achieving Policy Coherence

- Immunization to be included in revised WHO Antenatal Care Guidelines in 2016
- Clinical guidance for the evaluation of new vaccines in pregnancy under development
- Exploring use of prequalification to promote more permissive language in package inserts
- Strategies to assure all-year supply of influenza vaccines for countries in sub-tropical and tropical climate zones
Facilitate RSV Vaccine Development with a focus on Low and Middle Income Country populations

- Develop consensus guidance on *trial design* and *endpoint measures* including an assessment of severity of disease; and consensus assessment of regulatory considerations and concerns.

- Develop global roadmap for the RSV vaccine development
  - specify the priority unmet public health needs as strategic goals for vaccine development.
  - specify priority activities to be performed in order to accelerate vaccine development for LMIC, including in particular the development of consensus around the clinical endpoints for licensure and public health assessment of RSV vaccines.

- BMGF-funded effort coordinated by IVR (vaccine development, trial design), with EMP (standards, regulatory networks) and HSE (surveillance)
Findings from the following activities to be presented

- WHO Working Group to Evaluate Influenza Data to Inform Vaccine Impact and Economic Modelling (ongoing)
  - Assess key variables for influenza vaccine impact and economic studies
  - Burden of disease, vaccine performance
  - Methodological considerations

- WHO Maternal Influenza Meeting on New Data and Implementation, 25-26 March 2015
  - Review on new evidences related to maternal immunization (including interim findings from working group)
  - Implementation experiences, opportunities and challenges, partner activities

- BMGF Maternal Immunization Stakeholder Convening, 29-30 January 2015
With many thanks to IVR’s influenza team:

Justin Ortiz
Philipp Lambach
Mark Perut
Chiara Gerardi