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Outline

• Rationale
• WHO research agenda
• Delivery platforms: EPI, ANC, campaigns
• EPI considerations
• Summary
Why consider maternal immunization?

• Despite improvements in child survival
  ➢ Reductions in neonatal mortality (<1 mo) are slower than in children 1-59 months of age\(^1\)

• Of the 5.6 million deaths in children <5 years old,
  ➢ 2.6 million (46%) occurred in the neonatal period (0-28 days)\(^1\)

• 23% of neonatal deaths (and 11% of <5 deaths) are due to infectious causes, including pneumonia, tetanus, meningitis, and sepsis\(^2\)
  ➢ Potentially vaccine-preventable

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\(^1\) UN IGME Levels and Trends in Child Mortality 2017
\(^2\) WHO and Maternal and Child Epidemiology Estimation Group (MCEE) provisional estimates 2017
Two gaps in the traditional EPI schedule

Potential benefits of maternal immunization

- May protect neonates/infants in the first few weeks/months of life
  - through transplacental transfer of immunity
- May address morbidity and mortality associated with pre-term births
- May reduce morbidity and mortality among pregnant women
- May provide additional incentive to attend ANC services
- Has potential to improve overall quality of care for mothers and their newborns
Vaccines recommended by WHO for use in pregnant women

- **Generally recommended**
  - Tetanus (TT, Td)
  - Seasonal influenza

- **Specific situations**
  - Cholera, Yellow Fever
  - Meningitis A
  - Hepatitis A, B, E
  - JE, Polio, Pertussis

- **In development**
  - RSV
  - GBS
Successful implementation of routine maternal immunization will require harmonization of systems and services

• Innovative integration/collaboration will be needed at several levels
  ➢ EPI, ANC, MCH, etc.

• Pharmacovigilance/vaccine safety monitoring will need to be made more robust and comprehensive

• ANC services will need training and resources to incorporate vaccines into routine service delivery
  ➢ Including vaccine storage, administration, monitoring, and supply and data management

• Need to emphasize the importance of vaccination at the right time
  ➢ Unlike TTCV that could be given at any visit
To help close the perceived knowledge gap

- WHO research portfolio
  - The MIACSA project
  - The AMI project
Global recommendations and efforts to advance maternal immunization (MI)

2013
SAGE requested WHO to develop a process and a plan to move the maternal immunization agenda forward, creating alignment between data safety, evidence, public health needs and regulatory processes.

2015
SAGE encouraged WHO to promote more implementation research to generate generalizable data on the best ways to integrate maternal immunization into routine antenatal care in low resource settings.

2015
WHO Maternal Immunization Research Portfolio:
WHO surveyed global stakeholders on activities related to MI.
WHO maternal immunization research portfolio (2015)

- More than 60 projects included
- Clear activity gap:
  - Evaluation and optimization of vaccine delivery strategies
1) The Maternal Immunization and Antenatal Care Situation Analysis (MIACSA): rationale

• Jointly led by WHO Maternal and Child Health and the Immunization Departments

• Through a mixed methods approach, the study aims to:
  - Close information gaps on delivery of currently used maternal vaccines
  - Increase awareness among various country-level stakeholders for opportunities regarding future use of new maternal vaccines
  - Explore potential benefits resulting from delivery of MI through improved ANC systems
**MIACSA project timeline**

- **2016**
  - Desk review
    - Maternal health, MI data, vaccine delivery
    - LMICs: 136

- **2017**
  - Global online survey
    - Mat. immunization TTCV service delivery strategies
    - LMICs: 90
  - Telephone interviews
    - Enablers and barriers of MI service delivery at national level
    - LMICs: 30

- **2018**
  - Country visits
    - Enablers and barriers of MI service delivery (national, provincial & facility)
    - LMICs: 10

**WHO will share final data (report and a public database) at the beginning of 2019**
MIACSA data components

System capacity dimensions

Demand side
- Socio-cultural factors
- Socio-economic factors
- Health system interaction

Supply side
- Service delivery
- Health workforce
- Information systems
- Products, logistics, & infrastructure
- Financing
- Social/political leadership and commitment

Service Delivery Model

EPI EPI + ANC ANC

Programme responsibilities
- Procurement
- Planning and management
- Distribution
- Training and supervision

Surveillance
- Pregnancy/birth
- Disease/death
- Vaccine coverage
- Safety (AEFI)

Data recording systems

Use of multiple maternal vaccines

Performance

Protection at birth

TT2+ vaccination coverage

ANC

EPI

ANC
2) Advancing maternal immunization (AMI) project: Focus on RSV

- AMI is a PATH-led collaboration with WHO convening global, cross-sector experts

- Project objectives:
  - To establish a framework for informing, coordinating, tracking, and contributing to global efforts to advance RSV maternal immunization
  - To identify evidence needs to enable efficient, well-informed global and country decisions and requirements for rapid launch and uptake of RSV maternal vaccines in LMICs
  - To assess evidence gaps and priorities, and articulate the way forward for an RSV maternal immunization roadmap
  - To develop a plan to meet the needs for decision-making, rapid launch, and uptake
Preliminary results (AMI): Opportunities identified for successful introduction of RSV MI in LMICs

- Demonstrate safety and effectiveness (co-administration, expanded administration windows, co-morbidities)
- Generate/consolidate disease burden data
- Strengthen vaccine safety monitoring systems
- Identify appropriate and effective coordination mechanisms between EPI and MNCH programmes
- Estimate costs and budget impacts of RSV illness, maternal RSV vaccine, and delivery costs
- Policy and Advocacy
- Epidemiology
- Monitoring and Safety Surveillance
- Programmatic Considerations
- Health Economics and Financing
- Vaccine and Immunization Characteristics
Potential delivery platforms:

1. EPI
2. ANC
3. Campaigns
4. Others?
The EPI program: Successful experience with multiple new antigens over many years

**EPI strengths**

- Strong delivery platform with 40+ years’ experience
- Expansion from 6 original antigens to 23 today, and counting...
- Reaching >110 million infants at least 3 times annually, within the first year of life
- MNTE eliminated in all but 14 countries
Tetanus vaccination – Proof of concept for implementing maternal immunization

Reported TT2+ coverage and estimated NT deaths 2000-2016

>83% reduction in NT mortality since 2000
MNTE success has often been through efforts outside of routine immunization.

52 member states implemented TTCV SIAs between 1999 and 2014.

Countries that achieved elimination without SIAs: China, Eritrea, Namibia, Rwanda, South Africa, Zimbabwe.
Low ANC4 coverage and high ANC1-4 dropout: A challenge for maternal immunization

ANC1-ANC4 coverage by region 2015 (%)

- CEE/CIS
- EAPR
- LACR
- MENA

South Asia
ESAR
WCAR
World

Source: SOWC 2016

CEE/CIS - Central and Eastern Europe and the Commonwealth of Independent States
EAPR - East Asia and the Pacific
LACR - Latin America and Caribbean
MENA - Middle East and North Africa
South Asia - South Asia
ESAR - Eastern and Southern Africa
WCAR - West and Central Africa
Global antenatal care (ANC) coverage

- 86% of pregnant women access antenatal care with a skilled health personnel at least once
  - However, globally, it is estimated that more than 40% of all pregnant women were not receiving early antenatal care in 2013

- Globally, 62% of pregnant women receive at least four antenatal visits
  - 52% in sub-Saharan Africa
  - 46% in South Asia
Positive correlation between % of children fully immunized and # of ANC visits*

*Maria Clara Restrepo-Mendez, 2016 (from DHS and MICS surveys)
EPI considerations for RSV introduction
WHO framework for planning a new vaccine introduction (indicative EPI considerations)

1. Decision making
   a. The disease
   b. The vaccine
   c. The strength of the EPI program

2. Planning and management
   a. Updating plans and national policies
   b. Choosing the right strategy
   c. Vaccine management and injection safety

3. Monitoring and evaluation
   a. Coverage monitoring
   b. Disease surveillance
   c. Vaccine pharmacovigilance
Selected EPI considerations for RSV implementation
(assuming a decision is made to introduce in a country)
Vaccine delivery: Routine vs. campaigns

- **Campaigns**
  - Used widely for TTCV, but “narrow” target period will be a challenge for RSV
    - Other considerations include presentation, cold chain volume, temperature lability, etc.

- **Routine**
  - Need to build on integration between TTCV and antenatal care (ANC) services
    - Good collaboration between EPI and MNCH is necessary (reduce “silo effect”)
      - Example: Availability of cold chain equipment outside of the EPI clinics?
    - Low rate of ANC4 coverage (especially if RSV targets last trimester)
    - Women who start ANC late in pregnancy (need for pre-pregnancy counselling?)
    - Implementation likely to be more complex than TTCV
      - Need to inform/train/implement changes to both EPI and ANC (RMNCH) services
Coordination with the private sector

- In many countries, the private sector provides a significant proportion of ANC services
  - More strategic efforts needed to engage the private sector
    - Vaccine availability in the private sector
    - Training of private health workers
    - Liability and indemnity issues (AEFIs)
    - Monitoring and evaluation
      - Data tools
      - Reporting structures
Health worker training and social mobilization

- Training beyond traditional vaccinators
  - Plan to increase funding and human resource needs beyond usual levels

- Decision on which cadre of health staff will administer the MI vaccines
  - Within ANC clinics versus referral to EPI clinics?
  - Vaccinators, midwives, or obstetricians?
  - Adaptation of national policies needed in some countries
Monitoring and evaluation

- **Home-based records and reporting tools need to be updated**
  - In both public and private facilities
  - Private facilities may be unfamiliar with EPI data systems
    - Experience with TTCV data in most countries
- **Need to ensure adequate tracking of complete “series”**
  - Pre-delivery and post-delivery doses?
  - Mother-child health records???
Vaccine pharmacovigilance

- Being a special population, functional AEFI monitoring systems will be an advantage
  - Pharmacovigilance systems in most countries are quite rudimentary
  - Countries need to strengthen AEFI systems prior to RSV introduction
  - Any safety concerns or rumours may have a negative impact on the entire EPI program
Summary

- Most health systems have experience delivering vaccines to pregnant women
  - But not necessarily through the EPI programs

- Close coordination with non-EPI departments, and possibly the private sector will be needed
  - An important success factor in many settings

- Opportunities and best approaches will vary from country to country
  - Early engagement of key stakeholders is a critical element for success
  - Ongoing research projects may further inform best delivery strategy (e.g. AMI & MIACSA)
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