Update on Meningococcal A Vaccine Development and Introduction

WHO Product Development for Vaccines Advisory Committee Meeting (PD-VAC) @ Geneva, 7 - 9 September 2015
MenAfriVac introduction strategy

• Inducing strong herd protection
  ➢ single dose mass vaccinations in 1–29 year-olds, with high coverage in 26 meningitis belt countries

• Protecting new birth cohorts
  ➢ routine EPI immunization or periodic follow-up campaigns

• Enhancing surveillance and epidemic response
  ➢ throughout vaccine introduction and beyond
An integrated approach
PATH/WHO Meningitis Vaccine Project & partners 2001-2014

Research/Design
- 1996 Epidemic meningitis, high priority in Africa
- 1999 Conjugate meningococcal vaccines needed
- 2001 Project Launch
- 2002 African political will for affordable vaccines, and Business model defined
- 2003-04 Tech transfer to SIIL

Develop/Validate
- 2005 Phase I trial
- 2006-2013 Comprehensive vaccine development in India & Africa
- 2003-05 Enhanced disease surveillance and stockpile for epidemic response
- 2007-2008 Launch of carriage studies

Approve/Recommend
- June 2010 WHO Prequalification (1-29 year-olds) following DCGI licensure Jan. 2010
- 2010-2014 Regulatory approval at national level
- 2010 WHO/GACVS Recommendation & WHO/SAGE Policy
- 2014 Regulatory approval, policy for indication variation

Introduce/Optimize
- Sept. 2010 Phase I introduction in 3 selected districts
- Dec. 2010 Nationwide introduction in 3 countries
- 2010-2013 Enhanced manufacturing capacity (SIIL)

- 2016 Introduction in routine

Scale-up/Apply
- 2010-2016 Mass campaigns 1-29 year-olds in 26 countries in Africa
- 2011 Burkina Faso initial measurement of vaccine impact
- 2012 Chad demonstration and quantification of the vaccine effect
- 2014 Impact evaluation framework defined

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MenAfriVac rollout 2010–2016
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Number of Persons Vaccinated (Millions)

- 2010 Phase 1: 19.2
- 2010 Phase 2: 54.6
- 2011: 103.2
- 2012: 153.6
- 2013: 217.1
- 2014: 258.8
- 2015: 276.7
MenAfriVac vaccination campaigns and CTC

Use of Men A vaccine in a controlled temperature chain (CTC) during mass campaigns

Regulatory license variation/relabeling describing CTC option

CTC implementation needs preparation/training/supervision

Benin 2012 campaign: CTC implementation documented

Used in 2014 campaigns in Côte d’Ivoire, Mauritania, Togo

Very low wastage due to CTC (temperature or time excursions)
Vaccine coverage ~ 100%
No serious AEFI
Good understanding and compliance to CTC protocol
Excellent Health Care Workers’ acceptance of CTC approach

GAVI financial support
MenAfriVac routine introduction

• WHO update recommendations

- Countries completing mass vaccination campaigns should introduce meningococcal A conjugate vaccine into the routine childhood immunization programme within 1-5 years following campaign

- 1-dose schedule with routine vaccine administration at 9-18 months of age

- A one-time catch-up campaign should be conducted for birth cohorts born since the initial mass vaccination and outside the age range targeted by the routine immunization programme

  - MenAfriVac 5 micrograms should be used for routine immunization of infants and young children from 3 to 24 months of age
  - MenAfriVac (10 micrograms) should continue to be used for catch-up and periodic campaigns from 12 months of age onwards

MenAfriVac rollout 2010–2016

An additional ~70 million persons to be immunized in 2015-2016

2015
- Ethiopia (3rd/last campaign)
- DRC
- Guinea

2016
- South Sudan
- Guinea Bissau, RCA, Uganda
- Kenya
- Burundi, Eritrea, Rwanda, Tanzania

**Routine introduction to start in 2016**
- Ghana
- Burkina Faso, Chad, Mali, Niger, Nigeria, Sudan, Uganda, RCA …
Transitioning from campaigns to routine

- Completion of the MenA vaccine campaign roll out
- Introduction of the MenA vaccine into routine programmes
- Enhancing sustainable surveillance and outbreak response
- Promoting surveillance and research for impact evaluation
- Promoting vaccine R&D
Transitioning from campaigns to routine

• Enhancing sustainable surveillance and outbreak response
  ➢ Laboratory tools and processes
  ➢ Strategies to mobilize in country resources for lab. and diagnostic activities

• Promoting surveillance and research for impact evaluation.
  ➢ Case-based surveillance, vaccine effectiveness, investigation of vac. failures
  ➢ Meningitis Information Repository
  ➢ Modelling the impact of vaccine introduction and control strategies
  ➢ Economic impact on households and on the health system

• Promoting vaccine R&D
  ➢ Duration of immunity, correlate of protection
  ➢ Development/licensure of affordable Men polyvalent conjugate vaccines designed to meet country needs
THANK YOU