WHO position paper on Meningococcal A conjugate vaccine: updated guidance, February 2015

World Health Organization

Background

- A position paper on meningococcal vaccines was published in 2011 and its recommendations remain valid
- This update adds to the previous recommendations specifically concerning routine immunization of infants and young children in the African meningitis belt with meningococcal A conjugate vaccine

What's new?

- Preventive mass campaigns in 17 of the 26 countries in the African meningitis belt have been, or are in the process of being, implemented
- Over 217 million persons have received monovalent MenA conjugate vaccine
- Study in Chad provides evidence of the beneficial impact of the MenA conjugate vaccine on the incidence of serogroup A invasive disease and carriage

Meningitis Vaccine Project. (http://www.meningvax.org/index.php, accessed December 2014).

Daugla DM, Gami JP, Gamougam K, et al. Effect of a serogroup A meningococcal conjugate vaccine (PsA-TT) on serogroup A meningococcal meningitis and carriage in Chad: a community study. Lancet. 2014; 383: 40-47.

Vaccine types

- Two licensed formulations available:
  - **MenAfriVac**: 10 µg of purified Men A polysaccharide antigen conjugated with tetanus toxoid (PsA-TT) per dose
    - for use in those aged 1–29 years
  - **MenAfriVac 5 µg**: 5 µg of PsA-TT per dose
    - for use in infants and children aged 3–24 months

Current evidence on schedule and dosing

- Double-blind randomized controlled studies of monovalent MenA conjugate vaccine conducted in Ghana and Mali have established safety and immunogenicity
- MenA conjugate vaccine is immunogenic in a 1-dose schedule for those aged 9–24 months or in a 2-dose schedule for those aged 3–9 months

Meningitis Vaccine Project and Partners. *Results from the MenA conjugate vaccine (PsA-TT) randomized controlled trials in infants and young children: Executive summary.* Geneva, World Health Organization, 2014 (http://www.who.int/immunization/sage/meetings/2014/october/3_MenA_vaccine_trials_SAGE_01Oct2014.pdf?ua=1, accessed November 2014).

Current evidence on schedule and dosing

- Duration of protection >27 months after last dose unknown
- Modelling exercise demonstrated that immunization strategy resulting in lowest overall average annual incidence and longest time to resurgence was routine immunization at 9 months, beginning 5 years after the initial mass campaigns, with catch-up round targeting unvaccinated children aged 1–4 years

Karachaliou A, Trotter C. *Modelling long-term vaccination strategies with MenAfriVac® in the African meningitis belt: Executive summary prepared for SAGE, October 2014.* Geneva, World Health Organization, 2014 (http://www.who.int/immunization/sage/meetings/2014/october/2_Modelling_MenAfriVac_SAGE_summary_30Sep2014.pdf?ua=1, accessed November 2014).

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Co-administration

- In two large clinical trials in Ghana and Mali, non-inferiority of each of the MenA conjugate vaccine groups (MenA conjugate vaccine with other routinely administered vaccines) to the relevant control group (other routinely administered vaccines alone) was demonstrated for most of the vaccine comparisons
- Immunogenicity when co-administered with rotavirus and pneumococcal conjugate vaccines was not evaluated

Safety

- *Infants and young children:* Reactogenicity profile of MenA conjugate vaccine given concomitantly with routinely administered vaccines was shown to be similar to that of the concomitantly-given routine vaccines alone, with a comparable safety profile

- Both clinical studies from Ghana and Mali provide evidence that the two MenAfriVac formulations are well tolerated and safe

Safety

- *Pregnancy and lactation:* Observational study compared rates of pregnancy outcomes between pregnant women vaccinated in a mass campaign and unvaccinated pregnant women
- No significant differences in pregnancy outcomes
- Data are not available for lactating women
- Lactation is not considered a contraindication for administration of MenA conjugate vaccine

See No. 29, 2014, pp. 329-331.

WHO updated recommendations

- WHO emphasizes the importance of completing mass vaccination campaigns in individuals aged 1–29 years in all countries in the African meningitis belt, and the need to conduct high quality surveillance and vaccine programme evaluation in those countries

- The following recommendations are additional to those in the 2011 position paper

WHO updated recommendations

- WHO recommends that countries completing mass vaccination campaigns introduce meningococcal A conjugate vaccine into the routine childhood immunization programme within 1–5 years following campaign completion, along with a one-time catch-up campaign for birth cohorts born since the initial mass vaccination

- In areas where coverage with meningococcal A conjugate vaccine is less than 60%, periodic campaigns could be considered

WHO updated recommendations

- WHO recommends a 1-dose schedule at 9–18 months of age (based on local programmatic and epidemiologic considerations) by deep intramuscular injection, in the anterolateral aspect of the thigh
  - Vaccinate children who miss their dose as soon as possible
- If in a specific context there is a compelling reason to vaccinate infants younger than 9 months, give 2 doses at least 8 weeks apart starting at 3 months
- MenAfriVac 5 µg should be used for routine immunization of those 3 to 24 months of age; MenAfriVac 10 µg should be used for catch-up and periodic campaigns from 12 months of age onwards
- Need for a booster dose has not been established

WHO updated recommendations

- Data on co-administration with some other vaccines has been evaluated and found to be acceptable
  - Includes: diphtheria toxoid, tetanus toxoid, whole cell pertussis, hepatitis B, *Haemophilus influenzae* type b, oral poliovirus, yellow fever, measles and rubella vaccines
- No evidence exists for co-administration with rotavirus vaccine, pneumococcal conjugate vaccine or inactivated polio vaccine
  - Absence of data should not discourage co-administration

WHO updated recommendations

- Vaccination of pregnant women is safe, as assessed in a well-conducted observational study, and they should be vaccinated if in the age range targeted by the mass vaccination campaigns

For more information on the WHO Meningococcal A position paper, please visit the WHO website:

www.who.int/immunization/documents/positionpapers

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