GRADE Table 04. Safety of MenA conjugate vaccination in immunocompetent children (3 to 24 months of age)

Population : Immunocompetent children aged 3–24 months
Intervention: One or two doses of MenA conjugate vaccine (5 µg dosage)
Comparison: No MenA vaccination
Outcome : Serious adverse events following immunization

What is the incidence of serious adverse events following any dose of MenA conjugate vaccine in immunocompetent children aged 3–24 months?				
			Rating	Adjustment to rating
Quality Assessment	No. of studies/starting rating		2[1]/ RCT	4
	Factors decreasing confidence	Limitation in study design	None serious	0
		Inconsistency	None serious	0
		Indirectness	None serious	0
		Imprecision	None serious	0
		Publication bias	None serious	0
	Factors increasing confidence	Large effect	Not applicable	0
		Dose-response	Not applicable	0
		Antagonistic bias and confounding	Not applicable	0
	Final numerical rating of quality of evidence			**4**
Summary of Findings	**Statement on quality of evidence**			We are very confident that the true effect is close to the estimated effect on health outcome.
	Conclusion			We are very confident that the risk of unsolicited health outcomes in children aged 3–24 months following vaccination is low, as serious adverse reactions following any dose of MenA conjugate vaccine are rare.

[1] Two double blind, randomized clinical studies were conducted, PsA-TT-004, involving 1200 healthy infants in Ghana, and PsA-TT-007, involving 1500 healthy infants in Mali. The MenA conjugate vaccine was co-administered with other vaccines routinely administered in this age group. A total of 3315 doses of Men A conjugate vaccine (PsA-TT vaccine) were given in the two studies at various dosages (10 µg, 5 µg, and 2.5 µg), including 1270 doses of PsA-TT 5µg vaccine. 1179 and 472 infants received a first and second dose of MenAfriVac 10 µg, respectively, while 800 and 470 infants received a first and second dose of MenAfriVac 5µg. PsA-TT-004 reported two serious adverse events (SAEs) related to vaccination: one case of febrile seizure that occurred on the day of vaccination and resolved within 24 hours in a 12-month-old child who received MenAfriVac 10 µg with DTwPHBVHib, and one case of facial oedema with onset on the day of vaccination and resolved within 48 hours in a 9-month-old child who received MenAfriVac 10 µg alone. In PsA-TT-007 all SAEs were considered unrelated to vaccination. In both studies, rates of SAEs were similar between PsA-TT groups and the control group, which received only the routinely administered vaccines. The satisfactory safety profile of MenAfriVac 10 µg had been assessed in prior clinical trials conducted among the 1 –29 year-old individuals and during mass campaigns conducted among over 50 million 1–29 year-olds (see WER No. 30, 2011, pp. 321–324) representing a total of over 200 million vaccinated persons (see Meningitis Vaccine Project. http://www.meningvax.org/index.php, accessed November 2014).

Reference List

1. PsA-TT-004 In 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).
2. PsA-TT-007 In 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).
3. Data to be published: Meningitis Vaccine Project. Protocol No. PsA-TT-004. Final version 1- 30 October 2007-Amendment 1- 15 May 2008- Amendment 2- 23 September 2010.
4. Data to be published: Meningitis Vaccine Project. Protocol No. PsA-TT-007. Final version 1- 20 October 2011-Amendment 1-8 December 2011.