GRADE Table 7. What is the risk of serious adverse events following vaccination with inactivated Vero cell-derived JE vaccine?

Population : Immunocompetent individuals
Intervention: Two doses (primary series) of inactivated Vero cell-derived vaccine
Comparison: Placebo/no vaccination/other JE vaccine
Outcome : Serious adverse events

What is the risk of serious adverse events following vaccination with inactivated Vero cell-derived JE vaccine?				
			Rating	Adjustment to rating
Quality Assessment	No. of studies/starting rating		11 RCTs[1]	4
	Factors decreasing confidence	Limitation in study design	Serious[2]	-1
		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			**3**
Summary of Findings	**Statement on quality of evidence**			**Evidence supports a moderate level of confidence that the true effect lies close to that of the estimate of effect on health outcome**
	Conclusion			**Inactivated Vero cell-derived JE vaccine has an acceptable safety profile.** ***Based on a review of data on IXIARO***

[1]Two pooled analyses of 7 clinical studies (N=3558 vaccinated with IXIARO) and 10 clinical studies (N=4,043 vaccinated with IXIARO) have been published. In adults there was comparable tolerability and reactogenicity with placebo (adjuvant alone) and mouse brain-derived JE vaccine except for local reactions. A significantly lower frequency of severe local reactions was reported for IXIARO compared to mouse brain-derived JE vaccine. In a clinical trial of children aged ⩾2 months to < 1 year in the Philippines, a similar percentage of participants receiving IXIARO (N=131) or Prevnar (N=64) experienced solicited (58.0% vs. 59.4%), unsolicited (72.5% vs. 65.6%), and serious (0% vs. 1.6%) adverse events up to Day 56 after the first vaccination (European Public Assessment Report 2013).

[2] This vaccine has had limited use outside of clinical trials. Post-marketing data are published for the first 12 months of use (Schuller 2011). The ability to detect less common serious adverse events is limited.

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placebo-controlled phase 3 trial of the safety and tolerability of IC51, an inactivated Japanese encephalitis vaccine. J Infect Dis. 2008 Aug 15;198(4):493-9.