GRADE Table 9. What is the risk of serious adverse events following vaccination with live recombinant JE vaccine?

Population : Immunocompetent individuals living in JE-endemic areas
Intervention: One dose of live recombinant JE vaccine
Comparison: Placebo/no vaccination/other JE vaccine
Outcome : Serious adverse events

What is the risk of serious adverse events following vaccination with live recombinant JE vaccine?				
			Rating	Adjustment to rating
Quality Assessment	No. of studies/starting rating		10 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			**Live recombinant JE vaccine has an acceptable safety profile.** ***Based on a review of data on IMOJEV***

[1]10 RCTs contributing approximately 4,000 participants contributed safety data. In children 12 months to 18 years IMOJEV live recombinant vaccine had a safety profile comparable with licensed vaccines (Hepatitis A and varicella zoster) in terms of frequency and severity of local and systemic adverse reactions (Chokephaibulkit 2010, Feroldi 2012, Feroldi 2013). There was lower frequency of fever, injection site erythema and swelling after the first compared to second dose. Table 9 also shows the comparability in safety profiles between CD.JEVAX and IMOJEV. IMOJEV also has a comparable safety profile to MMR vaccine when administered to children 12-18 months in Taiwan (Huang 2014). In adults in two RCTs, comparable tolerability and reactogenicity with placebo and a mouse brain-derived JE vaccine were seen with the exception of local reactions (Torresi 2010). Significantly lower frequency of local adverse reactions was reported for IMOJEV than mouse brain-derived vaccine JE-VAX. The majority of adverse events was mild to moderate and resolved within a few days. Only one vaccine related serious AEFI (Pyrexia) was reported within the first month of vaccination and none during a 6-month follow-up. No case of death occurred (Torresi 2010). In addition, two serious adverse events (acute viral illness) possibly

related to vaccination with IMOJEV were reported during clinical development in adults (Australian Public Assessment Report 2010).
[2]This vaccine has had limited use outside of clinical trials. The ability to detect less common serious adverse events is limited.

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Clinical Studies

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