GRADE Table 8. What is the risk of serious adverse events following vaccination with live attenuated JE vaccine?

**Population**: Immunocompetent individuals  
**Intervention**: One dose of live attenuated JE vaccine  
**Comparison**: Placebo/no vaccination/other JE vaccine  
**Outcome**: Serious adverse events

<table>
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<tr>
<th>Rating</th>
<th>Adjustment to rating</th>
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<td>4 RCTs$^{1,2}$</td>
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**Factors decreasing confidence**
- Limitation in study design: None serious
- Inconsistency: None serious
- Indirectness: None serious
- Imprecision: None serious
- Publication bias: None serious

**Factors increasing confidence**
- Large effect: Not applicable
- Dose-response: Not applicable
- Antagonistic bias and confounding: Not applicable

**Final numerical rating of quality of evidence**: 4

**Statement on quality of evidence**: Evidence supports a high level of confidence that the true effect lies close to that of the estimate of effect on health outcome

**Summary of Findings**

**Conclusion**: Live attenuated JE vaccine has an acceptable safety profile.  
*Based on a review of data on CD.JEVAX*

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$^1$Four clinical studies of 1,256 participants contributed to the safety assessment. In children 9 months to 6 years, live attenuated SA 14-14-2 had moderately higher frequency and severity of local and systemic adverse events, including fever, compared to live recombinant vaccine (Feroldi 2014; Kim 2013). No vaccine-related serious adverse reactions or deaths were reported in RCTs (up to 7 months follow up) except for two cases of pyrexia in children aged 12-23 months.  

$^2$Post-marketing surveillance has also been done. Based on 23 million doses distributed between 2005-2012, 1426 adverse events were reported (61 per million doses), although this is an underestimate as is typical in particular with developing passive surveillance systems. Case reports were also reviewed, as was an observational study.
Clinical Studies


Kim DS, Houillon G. A randomized study of the immunogenicity and safety of Japanese encephalitis chimeric virus vaccine (JE-CV) in comparison with SA 14-14-2 vaccine in children in South Korea. 8th World Congress of the World Society for Pediatric Infectious Diseases (WSPID) - Nov. 19-22, 2013, Cape Town, South Africa.


Post-marketing surveillance and case reports

