GRADE Table 4. Vaccine safety of varicella vaccination in immunocompetent individuals (monovalent vaccine)

Population: Immunocompetent individuals
Intervention: Varicella vaccination (one dose)
Comparison: Placebo/ no vaccination
Outcome: Serious adverse events

In immunocompetent individuals, what is the incidence of serious adverse events following any dose of varicella vaccination?				
			Rating	Adjustment to rating
Quality Assessment	No. of studies/starting rating		12/ RCT[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**			**We are moderately confident in the estimate of effect on health outcome. The true effect is likely to be close to the estimate of the effect**
	Conclusion			**Our confidence in the estimate of the effect is moderate that incidence of serious adverse events following one or two doses of varicella vaccination is low. Overall few reports and low incidence of serious adverse events in RCTs, observational studies and post-marketing surveillance data. Despite overall low incidence of serious adverse events, incidence after first dose of vaccination is higher than after second dose.**

[1] 7 RCTs Ferrera et al. 2009 ; Gatchalian et al.2004 ; Lau et al. 2004 ; Parment et al. 2003 ; Ramkissoon et al. 1995 ; Shinefeld et al. 2002, Weibel 1984), 5 observational studies (Black et al. 1999 ; Chaves et al. 2009 ; Ozaki et al. 2000, Sharrer 2001, Galea 2008) assess the vaccine safety of one dose of varicella vaccination. Consistent findings across studies, overall low incidence of serious adverse events
[2] Small number of study participants to assess very rare serious events

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