Table 6. GRADE Evidence Profile: Should RSV vaccination vs. no vaccination be used in immunocompromised patients (adults and children)?

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	RSV vaccination	no vaccination	Relative (95% CI)	Absolute (95% CI)		
RSV-associated hospitalization in immunocompromised adults												
5[6, 7, 12, 13, 14]	non-randomised studies (case-control studies)	serious[a]	not serious[b]	not serious	not serious	none[c]	9063 cases 139315 controls		**VE: 68%** (64-72) Note: OR 0.32 (0.28 to 0.36)	-	⨁⨁⨁◯ Moderate[a,b,c]	CRITICAL
							-	1.0%		678 fewer per 100,000 (from 718 fewer to 638 fewer)		
Critical illness in immunocompetent adults ≥60 yrs (ICU admission or in-hospital death or both)												
1[6]	non-randomised studies (case-control studies)	serious[a]	not serious	serious[d]	not serious	none	262 cases 26669 controls		**VE: 81%** (52-92) Note: OR 0.19 (0.08 to 0.48)	-	⨁⨁◯◯ Low[a,d]	CRITICAL
							-	0.2%		162 fewer per 100,000 (from 184 fewer to 104 fewer)		
Serious adverse events (SAEs) in overall adults ≥60 yrs												
3[9,10,11]	randomised trials	not serious[e]	not serious	not serious	not serious	none	1795/37187 (4.8%)	1732/36845 (4.7%)	**RR 1.03** (0.97 to 1.09)	1 more per 1,000 (from 1 fewer to 4 more)	⨁⨁⨁⨁ High[e]	CRITICAL
Gullian-Barre Syndrome (GBS) in overall adults ≥60 yrs												
1[7]	non-randomised studies (before-after studies)	serious[a]	not serious	not serious	serious[f]	none	102/4746518 (0.0%)	0.0%	**RR 2.1** (1.5 to 2.9)	0 more per 100,000 (from 0 fewer to 0 fewer)	⨁⨁◯◯ Low[a,f]	CRITICAL
Exacerbation of immunocompromising or autoimmune condition												
0							No comparative evidence informing this outcome was identified.				-	IMPORTANT

CI: confidence interval; OR: odds ratio; RR: risk ratio

Explanations

a. Unknown confounding cannot be ruled out

b. Although statistically significant heterogeneity was observed (I-squared 70%), 4 out of 5 studies revealed clinically meaningful vaccine effectiveness rates - not rated down.

c. Large effect. However, not rated up for concerns of possible residual confounding

d. Based on indirect evidence in immunocompetent adults

e. Loss to follow-up was similar in both groups - not rated down

f. I-squared 74%