

Table Va

Authors: Wiersma S, Ott J				
Does single dose of inactivated hepatitis A vaccine provide long-term protection against HAV-related disease and fulminant hepatitis A?				
		Rating	Adjustment to rating	
Quality Assessment	No. of studies/starting rating		2 observational	2
	Factors decreasing confidence	Limitation in study design	Serious ¹	-1
		Inconsistency	None serious	0
		Indirectness	None serious	0
		Imprecision	None serious ²	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			1
Summary of Findings	Statement on quality of evidence		Our confidence in the estimate of the effect on the health outcome is very limited.	
	Conclusion		Two to three years after a single dose inactivated hepatitis A vaccine program there is evidence for a decrease in both, hepatitis A incidence³ and fulminant hepatitis A⁴ among hepatitis A cases.	

¹ Source of data was public health surveillance. Not all cases detected received single dose because the private sector uses two dose vaccination and public sector uses single dose. The private sector accounts for approximately 12% of vaccinated children. Decreases in hepatitis A

case rates pre and post introduction of universal hepatitis A immunization policy could be partially associated with natural immunity.

² Incidence reductions in age-groups and vaccine use regions were all statistically significant.

³ HAV incidence pre-immunization program: 85.5/100000 mean incidence versus post-immunization program (2 years after): 88% decrease, i.e. 10.3/100000.

⁴ Cases of HAV-associated fulminant hepatic failure (FHF) pre-immunization program: 54% (165/304) of FHF cases; post-immunization program (3 years after): 27.7% (18/65) of FHF cases.

Bibliography Table Va

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Table Vb

Authors: Wiersma S, Ott J				
Is there evidence for long-term sero-protection achieved by single dose vaccination with inactivated hepatitis A vaccine, as measured by GMT of anti-HAV and seroprotection rate (SPR)?				
			Rating	Adjustment to rating
Quality Assessment	No. of studies/starting rating		6 observational ¹	2
	Factors decreasing confidence	Limitation in study design	None serious	0
		Inconsistency	None serious	0
		Indirectness	None serious	0
		Imprecision	Non serious ²	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			
Summary of Findings	Statement on quality of evidence			Our confidence in the estimate of the effect on sero-protection is limited.
	Conclusion			There is evidence for 10.6 year sero-protection achieved by single dose vaccination of inactivated hepatitis A vaccines (GMT of 24 (95% CI: 14-41))³, SPRs ranging from 53.8-95.1%, depending on follow-up time.

¹ Adults and children were included in these studies.

² The measurable outcomes considered in the studies were SPR and GMT and were presented for ranges of follow-up periods only. However, immune responses to booster doses was obvious

and independent of time since initial vaccination suggesting immune memory was induced by single dose vaccination.

³ Hatz et al. 2011. N= 130 adults, 26 followed-up until month 9-128, SPR (anti-HAV AB concentrations =>10mIU/ml), 98-128 months: 53.8%; GMC, 98-128 months: 24 (95% CI: 14-41)

Bibliography Table Vb

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