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Question: Should primary hepatitis B series be used for long-term protection against hepatitis B virus infection?

Setting: General population (global)

Conclusion: The evidence for long-term protection of HepB by outcome is as follows: 1) High quality evidence to support effectiveness of a primary series of HepB to prevent any HBV infection at 15 years post vaccination of infants. 2) High quality evidence to support effectiveness of a primary series of HepB to prevent chronic HBV infection at 15 years post vaccination of infants. 3) Low quality evidence to support effectiveness of a primary series of HepB to prevent HBV infection at up to 22 years post-vaccination of infants.

Quality assessment						Summary of Findings	Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Quality	
hepatitis B infection (follow-up mean 15 years; anti-HBc)							
1 ¹	randomized trials	no serious limitations	no serious inconsistency	no serious indirectness ³	no serious imprecision	⊕⊕⊕⊕ ² HIGH	CRITICAL
chronic hepatitis B infection (follow-up mean 15 years; HBsAg)							
1 ¹	randomized trials	no serious limitations	no serious inconsistency	no serious indirectness ³	no serious imprecision	⊕⊕⊕⊕ ² HIGH	CRITICAL
hepatitis B infection and chronic infection (various follow-up; anti-HBc and HBsAg)							
34 ³	observational study	no serious limitations	no serious inconsistency	no serious indirectness	no serious imprecision	⊕⊕○○ LOW	CRITICAL

¹ One RCT in the Gambia with over 120,000 subjects has conducted interim analysis showing high efficacy against infection and chronic infection at 15 years follow-up.

² This study calculated a VE (95% CI) 67.0 (58.2–74.6) against anti-HBc and 96.6 (91.5–100) against HBsAg.

³ A review published in 2005 by Fitzsimons et al cited 26 studies (plus the Gambia RCT) that studied HepB recipients. These studies have had follow-up periods of 4-15 years post vaccination. A further search of the English language literature in Medline was conducted for studies published since the time of this review with follow-up of 10 or more years. This search resulted in 8 additional studies with evidence of protection up to 22 years post vaccination of infants. A total of 34 observational trials using both PDV and RV showed consistent results in regard to long-term protection against infection.

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