

## Revised WHO position paper on hepatitis B vaccine, Oct 2009 - the abridged version - (draft 22 Sept 2009)

The revised position paper of Oct 2009 replaces the corresponding document published in the Weekly Epidemiological Record in July 2004. In addition to the updated text, it provides links to selected references as well as to 4 tables grading the level of scientific evidence for some key conclusions.

**Background:** It is estimated that about 2 billion people worldwide have been infected with hepatitis B virus (HBV); 360 million are chronically infected, of whom 600 000 individuals die each year from HBV associated liver cirrhosis or hepatocellular carcinoma. In highly endemic countries, HBV transmission occurs mainly perinatally or in early childhood, whereas in low endemic areas, HBV is more often contracted later in life, either through sexual contact or the use of contaminated needles. Unless vaccinated at birth, the majority of children born to contagious mothers (HBsAg carriers) become chronically infected.

Hepatitis B vaccine (only recombinant vaccine available) exists as monovalent formulations or in fixed combination with other vaccines such as DTP. Worldwide experience and extensive reviews by independent expert committees, including WHO's Global Advisory Committee on Vaccine Safety (GACVS) confirm the excellent safety profile of this vaccine.

As of 2008, 177 countries had incorporated hepatitis B vaccine in their national infant immunization programmes and about 69% of the 2008 birth cohort received 3 doses of the vaccine. However, the first dose was administered within 24 hrs of birth in only about 27% of the cases (2006 data).

**Recommendations:** All infants should receive their first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours. This is crucial in areas of high hepatitis B endemicity, but important even in intermediate and low endemicity areas. Delivery of hepatitis B vaccine within 24 hours of birth should be a performance measure for all immunization programmes.

To complete the primary series the birth dose should be followed by 2 doses, e.g. at the time of the first and third doses of DTP vaccine, or, if programmatic more convenient, by 3 doses coinciding with DTP or other routine infant vaccinations. Minimum interval between doses is 4 weeks. There is no evidence to support the need for a booster dose following 3 (or 4) doses of hepatitis B vaccine in routine immunization programmes.

Catch-up vaccination of children should be considered for cohorts with low coverage. The need for catch-up vaccination in older age groups, including adolescents and adults, is determined by the baseline epidemiology of HBV infection in the country. The importance of vaccinating people with particular risk factors for acquiring HBV infection is emphasized.

A comprehensive approach to eliminating HBV transmission must address infections acquired perinatally and during early childhood, as well as those acquired by teenagers and adults. WHO strongly recommends that all regions and associated countries develop goals for hepatitis B control appropriate to their epidemiological situation.

Process indicators and the use of outcome measures are critical to verifying achievement goals. Serological surveys of HBsAg prevalence supplemented by surveillance for acute disease and collection of mortality data, will serve as the primary tool to measure the impact of immunization and achievement of the control goals.

