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## INTRODUCTION

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More than one third of the world's population has been infected with hepatitis B virus (HBV). It is estimated conservatively that there are 350 million chronic carriers of hepatitis B. Many are lifelong carriers, although not all are infectious, and some will clear the virus after varying intervals of many months or years.

Despite overwhelming evidence to the contrary, the significance of hepatitis B as a major cause of morbidity and mortality – including deaths from hepatocellular carcinoma – is sometimes underplayed. In fact, between 5% and 10% of adults and up to 90% of infants infected with HBV will become chronic carriers. Among these, 25% will develop serious liver disease as a result of hepatitis B infection, including chronic hepatitis, cirrhosis, and hepatocellular carcinoma. The latter is among the 10 most common cancers in the world, with a particularly high incidence in the South East Asian and Western Pacific regions and in sub-Saharan Africa – regions where HBV infection is highly endemic. Up to 80% of cases of hepatocellular carcinoma can be attributed to hepatitis B, which is second only to tobacco among the known human carcinogens.

The WHO has estimated that hepatitis B results in one to two million deaths every year worldwide. In Europe alone, it has been estimated that there are one million people infected

with HBV every year. Of these, about 90 000 will become chronic carriers and about 22 000 will eventually die from cirrhosis or hepatocellular carcinoma. Clearly, hepatitis B is an infection of major public health importance.

HBV is a DNA virus appearing by electron microscopy as a large, double shelled particle. The genome contains four open reading frames, comprising the pre-S/S gene, the pre-core/core gene (also encoding for the e antigen) the DNA polymerase gene, and the X gene. Much emphasis has recently been placed on the S, core and X genes, because of the emergence of mutations in the S, pre-S1, pre-S2, precore, and X regions. These are all of potential importance in terms of disease severity, prognosis, and vaccine efficacy.

The development of vaccines has been one of the great successes in preventive medicine. The first generation hepatitis B vaccines are plasma derived and are still used in many parts of the world. In a number of other countries, genetically engineered (recombinant) vaccines – most of which are yeast derived – have replaced the plasma derived vaccines. A new generation of vaccines is currently under development, incorporating both the pre-S1 and pre-S2 proteins as well as the surface antigen.

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