SCOPE AND JUSTIFICATION OF THE STUDY

i) The proposed study in the chronic HBV infected Indian patient families has important epidemiological, clinical, virological and preventive aspects. A thorough investigation into the modes of spread of HBV infection in the young and adult population in our country is urgently required. In other countries, while the prevalence of hepatitis B infection is decreasing, the incidence is increasing in our country. Identification of the common modes of transmission of the infection would help in the development of specific hygienic methods and preventive strategies.

ii) The proposed study is the first comprehensive approach designed to determine the prevalence and profile of HBV mutants in India. Since, with the increasing duration of infection, the frequency of mutations increases, study of the family contacts, the highest risk group in endemic countries like India, is the most important population base for study of the HBV mutants. The proposed investigations are likely to throw light on the molecular characteristics of precore/core and surface mutants. A comparison of the mutant forms of family members could also help to unearth the mode of transmission of mutant HBV forms.

iii) The diagnosis of mutant HBV forms is generally suspected on the basis of serological patterns. An antiHBe positive, DNA positive individual is suspected to be having precore mutation. Similarly, an HBsAg negative, HBV DNA positive individual is believed to be infected with a surface mutant form. Whether these assumptions are correct in the Indian context or not can only be determined with certainty by sequencing studies. In the proposed study specific molecular approaches would be used to screen and confirm the presence of different HBV mutant forms. These molecular studies would also indicate the most common mutations of HBV prevalent in India and help to develop newer serological assays. Indirect outcome of this study would be to assess the efficacy of current therapeutic and vaccination strategies for India. If the mutant forms out weigh the wild type of the virus it would be worthwhile to look for new treatment stratagies. All these issues would also be of great significance not only for our country but the whole for Asia.