B immunization Indian Pediatr 1997, 34: 555-556.

2 Sehgal A, Gupta I, Sehgal R, Ganguly NK Hepatitis B vaccine alone or in combination with anti HB immunoglobulin in the perinatal prophylaxis of babies born to HBsAg carrier mothers Acta Virol 1992, 36: 359-366.

3 Poovorawan Y, Sanpanat S, Pongpulert W, Chumdermpadetsuk S, Sentrakul P, Safary A Protective efficacy of a recombinant DNA hepatitis B vaccine in neonates of HBeAg antigen positive mothers JAMA 1989, 261: 3278-3281.

4 Greeberg DP Pediatnc experience with recombinant hepatitis B vaccines and relevant safety and immunogenic studies Pediatr Inf Dis J 1993,12: 438-445.

5. Hadler SC, Francis DP, Maynard JE Longerm immunogenicity and efficacy of hepatitis B vaccine in homosexual men N Engl J Med 1986, 315: 209-214.

6. Zuckerman JN Non response to Hepatitis B vaccines and the kinetics of anti HBs production J Med Virol 1996, 50: 283-288.

7. del Conho R, Grosheide PM, Gerards LJ, Heijitink RA, Schalm SW Hepatitis B vaccination and preterm infants Pediatr Inf Dis J 1993; 12: 407-408.

Reply

Two important questions have been raised by Dr. Kartikeyan regarding Hepatitis B virus (HBV) immunization in Indian infants, after reviewing the paper from Chandigarh on neonatal immunoprophylaxis against vertical transmission. The investigators had measured antibody (Anti-HBs) levels against HBsAg during 13-12 months of follow up of infants given vaccine alone or vaccine plus Hepatitis B immune globulin (HBIg). The questions are: why were the antibody levels achieved by the infants low, and, if 10 meg doses induced only low immune response, should we accept the vaccine containing only 5 meg as recommended by one supplier? Dr. Karthikeyan recommends studies to determine if Indian infants have inherently low response to HBV vaccine, and to ensure that the vaccines on the market are of required potency. Are we sure that HBV vaccines are stored and shipped under proper cold chain? The questions and the recommendation are relevant, important and timely. The authors themselves had not discussed the immuogenicity issue in detail, except to point out the low immune response and to cite an early study in which even lower antibody levels were noted.

Some two years prior to the Chandigarh study, we had done a preliminary study just to make sure that the neonatal immunoprophylaxis as recommended on the strength of data from outside India could be replicated here. We offered counselling and HBsAg testing to pregnant women and recommended immunoprophylaxis for the infants of virus carriers. Some choose HBIg and vaccine, some chose only vaccine and a few refused both. The vaccine was identical to the one used in Chandigarh. The schedule was with 3 doses, one at birth, second at 6 weeks and the third at 5-6 months. Each dose contained 10 meg. The dose of HBIg was 10 IU per Kg body weight, given within 12 (up to 24) hours of birth. After one year of follow

up, our results were as follows. Of the 12 infants whose parents opted no treatment, 5 became virus carriers. Of 26 infants given passive and active immunization, one became a carrier for a protective efficacy of 93%. Of 30 infants given the vaccine alone, 2 had become carriers, for a protective efficacy of 86%. These results reassured us about the local validity of the international recommendations on immunoprophylaxis. Our results are somewhat similar to the results of the Chandigarh study, but there are some differences also. For example, we had less failures of treatment in those given both HBIg and vaccine (n = 1) than in t lose given only vaccine (n = 2). In the Chandigarh study, the reverse was true; only one infant among those given vaccine alone became a carrier, while 3 infants given both HBIg and vaccine became carriers. Perhaps we might attribute such differences to the relatively small numbers of infants in the two studies. However, we did not measure antibody levels and the Chandigarh data do raise the concern that Dr. Karthikeyan has rightly raised.

We might ask as to whose responsibility it is to ensure the quality of vaccines as well as to assure that Indian infants do respond adequately to the licensed and marketted vaccines. Undoubtedly t Lese are the responsibilities of the licensing authority and the quality control authority of the Ministry of Health and Family Welfare of the Government f India. The Indian polio vaccine fiasco is still fresh in our minds. All the new generation vaccines including the 2 typhoid vaccines, HBV vaccine, cell culture rabies vaccines, Hib vaccines and varicella and Hepatitis A vaccines are all quite high-priced and not everyone can afford them. Each dose of any of them is more expensive than the entire doses of all the vaccines under the universal immunization pro-gramme. What is our guarantee that we get good quality products and that they are satisfactorily immunogenic? The purpose in posing this here is not simply to find fault, but to offer assistance and constructive recommendations to our colleagues in the ministry. The Academy should take this issue seriously and offer to the government every necessary and possible help by way of technical expertise, testing facilities and data management. We are together in this pursuit of the prophylaxis of our children.

Academy members who work in postgraduate training centers or medical colleges also have the moral resp visibility to isolate such important questions and to investigate them systematically. There may not be glamour in such research, but I can assure you of a great sense of satisfaction when such important problems are solved on our own steam. Responsibility is the hallmark of freedom.

T. Jacob John,
Chairman, IAP Committee on Immunization, Thekkakora, 2/91, Kamalakshipuram, Vellore 632 002.