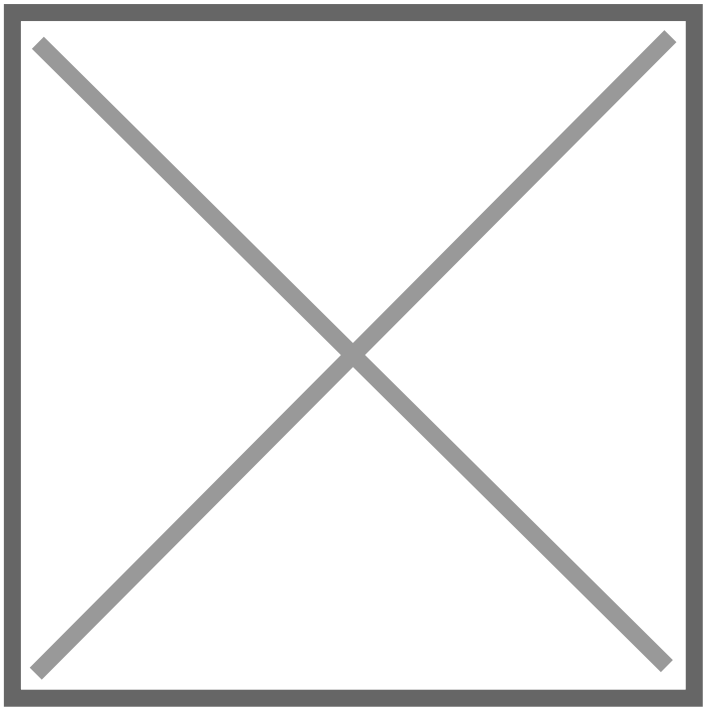
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A Cause for Concern

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Hepatitis B vaccine in National Immunization Program

A Cause for Concern

Four years after the launch of a pilot project for the introduction of Hepatitis B vaccine in the National Immunization Program in 2002, medical professionals have expressed concern over the inclusion of Hepatitis B due to lack of sufficient data and also the high cost outlay (Rs 500 crore each year) for universal immunization with Hepatitis B vaccine in India.

The government of India launched a pilot project for the introduction of hepatitis-B vaccine in the National Immunization Program on June10, 2002. Under this project, hepatitis B vaccine is administered to infants along with the primary doses of DPT vaccine in the 6th, 10th and 14th week. The project is presently being implemented in 33 districts and 15 metropolitan cities. Soon the hepatitis B vaccination program is to be expanded to cover 11 states across the country.

To begin with, monovalent hepatitis B vaccine has been used. Depending on the availability and cost of a combination vaccine, the government will evaluate and shift to the combo vaccine in future immunization programs. The vaccine and syringes are being made available by Global Alliance for Vaccine and Immunization (GAVI). Expenditure for IEC, training and monitoring budget is being incurred through the domestic funds.

India received assistance to the tune of $ 4.1 million for a period of two years from the Global Alliance for Vaccines and Immunization (GAVI) and the Vaccine Fund, based on an application from the Indian government and partners. The funds have been awarded to support the introduction of the hepatitis B vaccine into India's immunization program, which does not currently include the vaccine hepatitis B is a significant public health concern in India. It is estimated that 60 percent of liver diseases are due to hepatitis B infection and 80 percent of liver cancer cases in India are due to hepatitis B. The challenge of hepatitis B, like AIDS, is that it is "hidden" and its debilitating impact takes a long time to emerge. The difference is that there is an effective vaccine for hepatitis B, according to GAVI.

The project launched by the then prime minister, Atal Behari Vajpayee in 2002 is to be expanded in a phased manner during the Tenth Five-Year Plan, so that hepatitis B vaccination can be integrated into the routine immunization services and strengthens them.

The implementation of the hepatitis B vaccination project has started in 14 cities. The city of Patna has completed the hepatitis B training for medical officers and vaccinators but vaccination has not started due to preoccupation with Pulse Polio Eradication Program. Overall, the coverage of infants in all cities as in 2004 is about 98 percent (44,8,388 children vaccinated for third dose of hepatitis B against target of 4,55,688). Overall, the coverage of infants in all districts as in 2004 is about 76 percent (7,68,251 children vaccinated for third dose of hepatitis B against target of 1,001,484).

Concerns from medical professionals

The government has to have an outlay of Rs 500 crore per year for the implementation of immunization program of Hepatitis B vaccine. However, issues related to introducing Hepatitis B immunization has been a cause for concern among medical professionals in the country. The national president of the Indian Medical Association (IMA) (2005-2006), Dr Sudipto Roy set up a sub-committee under the chairmanship of Prof SK Mittal with Dr Dharam Prakash as convenor, to look into the issues concerned with the following objectives: to assess the prevalence of Hepatitis B in the country, and collect available data on deaths from hepatocellular carcinoma, to evaluate what the immunization program will cost the country, to look for evidence of the success of the pilot project, and to collect evidence from worldwide literature on the results of Hepatitis-B vaccination starting in the sixth week. The committee first met on October 19, 2005. It was decided to hold a national-level consultation on May 14, 2006 to discuss the issues related to Hepatitis B immunization. Dr Jacob Puliyel, co-chairman, sub-committee prepared a draft position paper on Hepatitis B.

A national consultation of experts was held on May 14, 2006, which was co-sponsored by Plan International (India). After discussions, the experts arrived at the following conclusions and made some recommendations on Hepatitis B vaccination in India.

Conclusion 1: On meta-analysis, the true prevalence of Hepatitis B in India among non-tribals is 2.1 percent (95 percent CI 1.8-2.5). This is the meta analysis of the data of point prevalence, not carrier rate. It was pointed out that chronic carriers have to be positive on repeat testing in two tests at least six months apart. The carrier rate is approximately 80 percent of the point prevalence rate. This corresponds to a chronic carrier rate of 1.6 percent.

Conclusion 2: Hepatocellular carcinoma constitutes only 1.6 percent of all cancers in India, hence is very rare. However, it is not clear how many of these are related to Hepatitis B. The estimated annual deaths attributable to hepatocellular carcinoma due to hepatitis B are only 5,000. A better marker of burden of Hepatitis B may be obtained by a registry counting cases of cirrhosis as about a third of cases of cirrhosis in adults is related to Hepatitis B. Reliable data on this is not available.

Recommendation: In view of these estimates, the cost efficacy of universal immunization with Hepatitis B needs to be re-evaluated.

Conclusion 3: Vertical transmission of infection from mother to child is an important mode of acquiring Hepatitis-B infection, especially in establishing chronic Hepatitis B carriers. The exact incidence of vertical transmission is not known in our country but it may be contributing between 30 and 40 percent of the pool of chronic Hepatitis B carriers.

Recommendation: Before launching any national program, it would be vital to assess the contribution of vertical transmission to the overall Hepatitis B carrier pool. If universal Hepatitis-B vaccination is to be carried out, the currently available data, though inadequate, would strongly favor initiation of Hepatitis B vaccination starting at birth, to derive maximum benefit from the program.

Conclusion 4: There is no scientific data from anywhere in the world that the schedule of 6, 10 and 14 weeks has been found to be effective in reducing the carrier rates of Hepatitis B. The pilot project carried out in Andhra Pradesh and Delhi with 6, 10 and 14 weeks has not been evaluated for its efficacy. We need to know the effect on carrier rates among the children who received the vaccine in the 6th, 10th and 14th weeks compared to the unvaccinated children.

Recommendation: It will not be advisable to initiate a national/ sub-national immunization program without proper evaluation of the pilot project.

Conclusion 5: The overall prevalence of chronic carrier rate among the tribal population is very high (19.4 percent (95 percent CI 15.3 Ã¢â?¬â?? 23.5) which is comparable to those living in the East Asian countries.

Recommendation: A well-designed epidemiological study is needed in this population to study the natural history of the disease. If necessary, a vaccination program, with first dose being given at birth, could be considered in these population groups.