

## Introduction of Hib Containing Pentavalent Vaccine in National Immunization Program of India: The Concerns and the Reality!

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The Global Alliance for Vaccines and Immunization (GAVI) recently sanctioned funds worth US\$ 165 million for introduction of a pentavalent combination vaccine (containing Diphtheria, Tetanus, Pertussis, Hepatitis B and Hib antigens) in to the routine immunization program of India(1). This combination vaccine will first be introduced in ten states (Andhra Pradesh, Himachal Pradesh, Jammu & Kashmir, Madhya Pradesh, Maharashtra, Kerala, Karnataka, Punjab, Tamil Nadu and West Bengal), and is expected to benefit more than 18 million children(1). This huge grant from GAVI will fund the first two years of pentavalent vaccination in these states, starting from 2010.

### **BURDEN OF HIB DISEASE IN INDIA: IS THERE ENOUGH EVIDENCE?**

GAVI and many other health agencies and groups believe that Hib disease is a serious and significant public health problem in India. In a recent statement to the lay press, Dr Panna Choudhury, President, Indian Academy of Pediatrics (IAP), commented, *“Routine use of Hib vaccine is an essential piece of a comprehensive pneumonia control strategy to reduce the disease’s terrible burden on children.”* According to the data provided by UNICEF and WHO, Hib is a leading cause of acute bacterial meningitis and important cause of severe pneumonia in Indian children. Approximately 410,000 (19%) of under-5 deaths in India are due to pneumonia out of which an estimated 70,000 are caused by the Hib(2).

Data from some developing countries such as Bangladesh, Chile and Malawi suggest Hib as a cause of over 20% of life-threatening childhood pneumonia(2). Small scale studies from India have documented case-fatality rate for Hib meningitis as 11%, and about 30% of survivors suffer from major disabilities(2).

There is a paucity of nation-wide data on the exact epidemiological burden of Hib disease in India, and figures provided by the agencies are based on broad estimates. This is one of the most contentious issues for Hib vaccine introduction in the National Immunization Program (NIP) of India. Some experts have questioned the data on Hib disease provided by the agencies, and concluded that the overall disease burden does not warrant universal immunization of children. However, there is now an emerging consensus among experts that the Hib disease does pose a significant health burden in India.

### **THE CONCERNS**

The greatest concern is regarding the long-term sustainability of the program: What will happen after two years when GAVI funding stands withdrawn? Who will bear the brunt of the expenditure incurred on introducing the vaccine all over the country? Will adequate stocks be available to meet the huge need, ensuring uninterrupted vaccine supply? Though the current grant is only for two years for 10 select states, GAVI alliance is hoping that the prices of this combination vaccine will fall drastically in next few

years once increased demand spurs the competition to hot up between vaccine developers.

Another concern is regarding impact of this vaccine on routine immunization, especially in states like UP, Bihar, and MP, where full immunization coverage rates are abysmally low at 30-40%. With such dismal rates, the proposed introduction may not have any substantial impact on the epidemiology of the illnesses covered through this vaccine, particularly the Hib disease. According to the explanation offered by the alliance, the introduction will help in reducing transmission of the disease due to “herd effect”, even when coverage of the vaccine is low. However, in the absence of sound data on the herd immunity of this vaccine, these assumptions seem to be highly optimistic. Another possible concern is: would introducing new vaccines in National schedule hinder the country’s efforts to expand immunization coverage for other more important diseases? Admittedly, there is an urgent need to bolster the system with more resources before burdening it further with introduction of new antigens. However, it can be argued that the introduction of a new vaccine may actually improve the routine coverage by added training, and increased awareness and demand among parents and caregivers. Further, being a combination vaccine, it will not require additional shots or visits, and can be easily merged with the existing schedule.

Many would argue that this decision is influenced more by commerce rather than dictated by the need of the country. Considering a big market in India, many vaccine manufacturers would make huge profits with this move. Such allegations can not be entirely refuted since these manufacturers are the key constituents of GAVI alliance. The role of international agencies and their nexus with multinational companies in influencing the public health priorities of developing countries has already been criticized on many occasions in recent times. The GAVI alliance, however, counters this allegation with the statement: “The decision to adopt Hib vaccine was not based on providing business to any particular manufacturer and the business will be offered to the manufacturer who best meets the needs of the country.”

## ROLE OF IAP AND FUTURE NEEDS

Can IAP take credit for this decision? Through its recommendations (made around 10 years back) to the Government regarding inclusion of Hib vaccine in the NIP, and by persisting with the demand through its representation to National Technical Advisory Group, IAP is entitled to take some credit. But on closer scrutiny, it was the WHO stand on Hib vaccine introduction in the NIPs of developing countries, and the fact that more than 150 countries around the globe are already using this vaccine, it became almost impossible for the Government of India to turn down the tempting GAVI offer for introduction of this vaccine in the national schedule. Nevertheless, IAP has to play a major role while drafting recommendations to the government for future introductions of ‘suitable’ vaccines. The onus is now on the IAP to not only devise impeccable guidelines on the vaccines for the existing and future needs, but to help government agencies in developing a well functioning sentinel based surveillance system to give an overall picture of the burden of all the diseases against whom mass vaccination drives are contemplated. The Government must also develop methods and means so that it can derive its own reliable data through well-planned epidemiological surveillance rather than relying on extrapolated figures from other countries or resorting to certain controversial methods like “Vaccine Probe” and “Impact Studies”, that look like a frantic attempt to justify inclusion of a vaccine in the countries where pre-introduction data are lacking.

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