Optional vaccines: a critical appraisal

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The national immunisation schedule includes BCG, DPT, oral polio and measles vaccines, besides DT and TT. Many more vaccines are now freely available in the country. The immunisation committee of the Indian Academy of Paediatrics has considered most of these vaccines 'optional' and not included them in the national immunisation schedule. However, there is no clarity about who should exercise this option: the physician or the parents.

One might expect that physicians would consider the various vaccines' merits and demerits, and inform parents accordingly. In actual practice, however, these decisions are made more on on the basis of personal bias than on well-informed debate. Unfortunately, in any such decision, affordability is the major determinant and often overrides scientific wisdom.

Need a sound strategy

There are many grey areas and lacunae in our understanding of infections and vaccines. It is prudent that we build our own epidemiological data to evolve a sound strategy in this area, though we may be forced to take some decisions temporarily in the absence of reliable data. It is also true that the epidemiology of infections keeps changing over time, requiring appropriate modifications in our immunisation strategies.

India may be considered a conglomeration of many countries within a country. A national policy must be evolved after considering many variables. One may justify selective protection of individuals with certain vaccines on a scientific basis (such as pneumococcal vaccine in splenectomised patients), but one must be cautious about the routine use of 'optional' vaccines. It is important to think beyond mere availability and affordability.

The merits of 'optional' vaccines for individual use must be considered on the basis of the degree of prevalence of the infection and disease; age prevalence of mortality, morbidity and sequelae of the disease; risk of severe disease in susceptible adults after weaning of vaccine-induced immunity; and the effects of childhood vaccination in modifying future epidemiology. Socioeconomic factors must be seriously considered before including an 'optional'vaccine in the national immunisation schedule. At present, only the Hepatiis B vaccine can be considered for such inclusion.

Hepatitis B vaccine

The quoted prevalence of Hepatitis B infection in India as 4.7 per cent has been questioned on the basis of selection bias and faulty interpretation. Most of the studies are based on a single serological test. Ideally carrier state is defined as persistence of Hepatitis B surface antigen over a period of six months. Subjects in the studies quoted have been mostly blood donors. This does not represent the status in the community at large. The corrected prevalence may be less than two per cent. Such a low prevalence may not justify inclusion of the Hepatitis B vaccine in the national immunisation schedule.

However, newborns and infants, if infected, are likely not to clear the antigen and thus contribute to the carrier pool in the community. It is therefore rational to consider immunising infants as early as possible, though routine adult immunisation may not be necessary. As the cost of the vaccine has come down drastically, it may be feasible to consider including this vaccine in the national immunisation schedule in the future.

'Optional' vaccines used in the private sector

These include the typhoid, HiB, varicella and Hepatitis A vaccines. Pneumococcal, meningococcal and influenza viral vaccines are rarely used routinely and are obviously not included in the national immunisation schedule.

The emergence of multidrug resistant typhoid fever would justify the use of the typhoid vaccine in vulnerable children (especially from the lower socio-economic group) exposed to unhygienic food and water. Of course, far more important is the availability of potable water and hygienic food and the rational use of antibiotics. Phenol-killed conventional vaccine is cheap and as efficacious as the new vaccines, but it is not manufactured at present.

Multicentric epidemiological studies in India have shown that 30 per cent of meningitis and pneumonia under the age of two years is caused by H.flu infection. Mortality and morbidity of such infections is severe, justifying protection. The vaccine is administered along with the DPT vaccine in infants. The use of this vaccine is limited now due to its cost but it deserves consideration whenever feasible.

Indian studies have reported a prevalence rate of varicella infection greater than 90 per cent in children less than 15 years of age in most parts of the country. Varicella is a benign disease in children and complications are rare. The incidence of encephalitis is around 1 in 100,000 infected children. Most of these children recover without sequelae, but the disease is known to be severe in adolescents and adults. Hence, childhood protection is not important.

Immunity induced by the varicella vaccine is expected to last for 15-20 years. Such an estimate is based on theoretical regression analysis. It is hoped that vaccine-induced immunity is boosted by natural exposure to infection and will continue to afford long-term protection. However, the epidemiology of infections keeps on changing. I have seen the disease recurring in a few children who are essentially immunocompetent. I have also seen the simultaneous occurrence of varicella and herpes zoster in two children. These manifestations represent a change in immune status of hosts in the community. If natural infection has a variable outcome, it is impossible to predict response to vaccination over a few years. Early childhood immunisation may leave adolescents and adults susceptible to developing severe disease. Breakthrough infections have been reported in immunised children though

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the attack rate and severity have been low compared to non-immunised children. It has been also noticed that the low titre vaccine administered at less than 12 months of age has poor immunogenicity. Hence, it may be ideal to consider vaccination in children older than 12-14 years of age if not infected by then.

Seroprevalence of Hepatitis A has been reported to be 50 per cent of those less than three years and 80 per cent of those less than eight years of age. Children from a high socioeconomic group and hygienic families are likely not to be exposed to infection. Hepatitis A is a benign disease in childhood but assumes severity in adolescents and young adults. Like the varicella vaccine, immunity induced by the Hepatitis A vaccine is expected to last for 15-20 years, after which adolescents are likely to be susceptible **if** exposed to natural infection. It is best to consider administration of this vaccine in children over 12 years of age if not naturally infected.

To summarise, the varicella and Hepatitis A vaccines should be reserved for older children if they are not already infected by then. The typhoid vaccine must be administered to all susceptible children and adults. The HiB vaccine is ideal for children less than two years old.

References:

1. Thyagarajan SP, Jayaram S, Mohanvalli B: *Prevalence of HBV in general population of India in Hepatitis B in India* (Ed) SKSarin, AKSinghal, CBS publishers and distributors 1996 p 9

2. John JT, Cherian T, Raghupathi P: Haemophilus Influenza disease in children in India- a hospital perspective *Pediatric Infectious Disease Journal* 1998, 17:S169-S171

3. IBIS group: Invasive Haemophilus influenza disease in India – a preliminary report of prospective multihospital surveillance *Pediatric Infectious.Disease. Journal*. 1998,17:S172-S175

4. Venkatraman AR, John TJ: Epidemiology of varicella in staff and students of a hospital in tropics *International Journal of Epidemiology* 1984, 13: 502-505

5. Dhavan PS, Shah SS, Alavares J.F: Seroprevalence of Hepatitis A virus in Mumbai *Indian Journal of Gastroenterology* 1998, 17(1): 16-18

Epidemiology and ethics in the Hepatitis B vaccine

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The current claims of Hepatitis B virus (HBV) carrier rate in India are highly exaggerated, unscientific and misleading. A series of errors is being made in estimating the burden of HBV disease and its significance. These errrors must be corrected, and we must scientifically assess the burden of morbidity, mortality and consequent loss of life-years due to HBV in India. Finally, we must also discuss the various options for a HBV vaccination strategy in India on the basis of cost effectiveness and logistical feasibility. We are unaware of any such exercise by the Indian Association of Paediatrics before its strong recommendation of universal immunisation of Indian children against HBV.

Frightening figures

Most doctors seem convinced about the overwhelming danger of HBV infection in India based on frightening figures put forth by experts who claim that the carrier rate in India is 4.7 per cent with an estimated carrier population of 42.5 million (1). These widely-quoted estimates, based on the results of 19 studies, suffer from three types of errors.

First, the studies are all one-time cross-sectional studies of prevalence of HBsAg positivity. Positivity is different from a carrier state — the persistence of infection for six months or more (2).

Second, many of these studies are based on data from blood bank donors, including professional blood donors who are known to have a higher prevalence of HBV infection. One study reports on dental professionals, another high risk group. These groups cannot be used to estimate prevalence in the general population.

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Finally, the average prevalence of 4.7 percent has been arrived at not as a weighted average but by calculating the simple average of the numbers in the individual studies.

A more accurate estimate of the carrier rate — a carrier being someone who has tested positive for HBsAg in two tests six or more months apart — using the same data in the 19 studies, and after excluding the professional blood donors and dental personnel and those studies in which the numbers tested are not mentioned (and taking into account the positive predictive value of the test being used currently) works out to be 1.42%, with a carrier pool of 12.75 million (3).

It is also important to note that, contrary to the current assertions (4), not all HBsAg positives are highly infectious. The prevalence of highly infectious carriers ("Hbe positives") is much lower than the estimate of 24.43 per cent of HBsAg positives or approximately 10 million (1). We arrive at the much lower figure of 3.26 million highly infectious carriers (3).

Is it a public health problem?

Some people have argued that HBV is a major public health problem. "Liver disease due to HBV infection is considered to be the fourth or fifth most important cause of mortality in the most productive period of life, 15-45 years (4). Approximately 25 per cent of carriers are expected to die of chronic sequelae of the infection — cirrhosis and primary hepatocellular carcinoma (5). In fact, the danger of chronic infection and chronic sequelae from HBV infection is much less than that. Recent observations suggest that the true rate of chronic infection is as low as one per cent in normal, immunocompetent young adults (6), not five per cent to 10 per cent. Even among these carriers, about two per cent clear the virus every year.

We do not have adequate data on prevalence of HBsAg positivity in