

## **Hepatitis B Immunization in Public Health Mode in India**

*Virologist's Perspective*

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**T**he Expanded Program on Immunization (EPI) was launched in 1974 by the World Health Organization (WHO), ostensibly to create an equitable vaccine delivery system in countries without public health infrastructure and accessible, affordable, quality healthcare [1]. So EPI would offer free service, made affordable to country budgets by enabling relatively low-paid, minimally trained health-workers to inoculate a few selected vaccines (BCG, DTP, OPV and measles). To monitor vaccine-delivery efficiency, coverage survey was designed. India adopted EPI in 1978 without measles vaccine and re-named it Universal Immunization Program (UIP) in 1985, after including measles vaccine.

The proximate purpose of UIP was vaccine delivery, but its potential was control of vaccine-preventable diseases (VPDs) [2]. In healthcare, immunization is to protect individual children, but in 'public health mode' it is for VPD control. Control means reduction of disease burden (incidence frequency) to pre-determined level, in planned time frame, and its documentation. Control trajectory and control status must be continuously monitored.

We have done well in making the vaccine delivery platform robust. Vaccine quality is assured; injections are safe. The national grid of cold chain is maintained well. Vaccine procurement and distribution are systematic. Periodic surveys monitor immunization coverage in States and Districts. Unfortunately gross disparities exist between States, between Districts, between urban and rural communities and between the rich and the poor; equity is yet to be achieved. A National Technical Advisory Group on Immunization (NTAGI) advises the program on the choice and mode of introduction of newer vaccines. In recent years, UIP has included vaccines against Japanese encephalitis (JE) in districts known to be recurrently affected; and vaccines against hepatitis B virus (HBV) and *Haemophilus influenzae* b (Hib) in a phased manner.

Our failure lies in UIP's inability to go beyond vaccine delivery. The inoculation schedule must obtain optimum immunological benefit and reduction in incidence of VPDs. UIP does not have in-house capacity to monitor these. That flaw resulted in not recognizing the failure of 3-4 doses of OPV (trivalent) to protect half of the vaccinated children [3]. Since UIP did not complain, WHO experts believed that OPV was performing well. In 2005, India still had endemic polio; on scrutiny they understood the fact of 'failure of vaccine' as the failure-factor, not failure to vaccinate. Very low vaccine efficacy meant no herd effect; hence virtually 100% of children had to be vaccinated repeatedly, unlike in other countries where near 85% coverage was enough. Damage had been done already: over the decades hundreds of thousands of children were paralyzed in spite of 3-4 doses of OPV and much time and funds were lost before bringing polio eradication on track using monovalent and bivalent OPVs designed for higher immunogenicity [3-5].

The immunological and epidemiological outcomes of rolling out JE, Hib and HBV vaccines are not being monitored as UIP has no capacity for that function. Introduction of HBV vaccine was pilot-tested in 14 cities and 33 Districts in 2002-03 and extended to 10 States in 2007-08. In 2009, the WHO was requested to assess vaccine delivery success, not outcomes. The National Polio Surveillance Project (NPSP, joint project of WHO and Union Government) assessed vaccine delivery efficiency [6]. Some flaws were detected but without correcting them, immunization was expanded to the entire country in 2011-12.

This issue of HBV vaccination outcome, raised in NTAGI in 2009, resulted in Indian Council of Medical Research (ICMR) agreeing to investigate immunological benefits. The results of this study designed by an Expert Committee are published in this issue of *Indian Pediatrics* [7].

The study was conducted in 5-11 year-old rural children in five districts in [earstwhile] Andhra Pradesh. HBV-vaccinated (born in 2003/2004, given 3 doses) and unvaccinated (born in 2001/2002) children were compared for HBV serology parameters. Anti-HBs was found in 53% of vaccinated and 18% of unvaccinated children – suggesting vaccine-induced immunity prevalence in only 35% of children. Part of the problem is waning immunity; the youngest (5-year-olds) had the highest anti-HBs prevalence, but even that was only 64%. These are not satisfactory results since HBV vaccine is highly immunogenic if scheduled properly. The relatively low immune response is corroborated by closely similar frequency of Anti-HBc (marker of HBV infection): 1.79% in unvaccinated and 1.05% in the vaccinated. The frequency of chronic infection (carrier state with HBsAg) was also equal (0.17% in unvaccinated and 0.15% in vaccinated).

HBV immunization ought to induce more than 95% seroconversion and significantly lower breakthrough infection frequency than in the unimmunized, and zero incidence of chronic infection. The results reported here call for immediate further investigations – on a much larger scale – to examine the influence of vaccination schedule in inducing optimum protection. If need be, we should design a more efficient schedule – in terms of the number of doses or the interval between the second and third dose. Getting less than optimum benefit for the investment is unfair to the people.

UIP is in urgent need of re-engineering, with in-built capacity to fulfil management principles : to measure and

document optimum outcomes – immunological and epidemiological – commensurate with the massive investment.

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## Utility of Hepatitis B Vaccination in India

### *Pediatrician's Perspective*

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**G**lobal health interventions are being scrutinized more closely than previously. According to an article published recently, the Center for Global Development in Washington is looking for evidence in real-life field conditions to ascertain whether large-scale health interventions have actually led to lower numbers of cases or deaths, and whether these improvements are sufficient

to justify the costs [1]. This issue of *Indian Pediatrics* includes a paper on limited evaluation of the effect of inclusion of hepatitis B (HB) vaccine in childhood immunization program in India [2]. The authors carried out a serological survey of children aged 5 to 11 years in rural Andhra Pradesh; 2674 of those surveyed had received HB immunization and 2350 had not received such immunization. Babies who get infected with the