

## Newer Vaccines in India

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### Abstract

**Background:** EPI was launched in India in the year 1978 four years after it was launched by WHO. The programme is now known as Universal immunization programmed. It was launched in India on November 1985. Vaccines are said to be very important public health tools for primary healthcare being critical for a nation's health security. Globally every country has its own vaccination schedule for which potent vaccines are available which are cost effective, operationally feasible and socially acceptable as well.

**Objective:** To review the newer vaccines being given in India.

**Conclusion:** The introduction of newer vaccines have often resulted in increased access to new and old vaccines in most documented cases which has resulted in necessary changes in the health and medical management practices.

**Keywords:** New vaccines; Hepatitis B; India; IPV

**Abbreviations:** HBV: Hepatitis B Virus; MDG4: Millennium Development Goal 4; Hib: Haemophilus Influenzae Type b; PCV13: 13-Valent Pneumococcal Conjugate Vaccine; PPSV23: pneumococcal polysaccharide vaccine; CRS: Congenital Rubella Syndrome; MMR: Mumps-Measles Rubella; VAR: Varicella Vaccine; NCHS: National Center for Health Statistics; RZV: Recombinant Zoster Vaccine; ZVL: Zoster Vaccine Live; DTaP: Diphtheria, Tetanus, and acellular Pertussis; IPV: Inactivated poliovirus vaccine.

### Introduction

#### Background

EPI was launched in India in the year 1978 four years after it was launched by WHO. The programme is now

known as Universal immunization programmed. It was launched in India on November 1985. It was launched to protect all children of the world against six vaccine preventable namely-diphtheria, whooping cough, tetanus, polio, tuberculosis by the year 2000 [1]. Vaccines are said to be very important public health tools for primary healthcare being critical for a nation's health security. Since 1999 national governments, international organizations as well as country governments refocused their attention on immunization, the GAVI Alliance was created and funding for immunization from donors and from country governments increased sharply.

Several least developed countries could not reach the recommended levels of health spending i.e. 5% of GNP since lion share of total spending in health is being borne by private health sector [2].

It is also evident that many countries could not achieve MDGS i.e. Millennium Development Goal 4 [MDG4] but now newer vaccines can fill that gap. Globally every country has its own vaccination schedule for which potent vaccines are available which are cost effective, operationally feasible and socially acceptable as well.

The success of an immunisation programme depends upon their national policies, whole hearted participation of the people at the local level where people think it's their programme meant for welfare. For a tropical country like India with its population of 1.3 billion people with addition of 28 million new births every year is absolutely true.

### Objective

To review the newer vaccines being given in India.

Based on the WHO UNICEF scoring system to determine vaccine priority, the following vaccines has been included in the list of immunization schedule in many states of India pentavalent vaccines, mumps, measles, rubella vaccines, the rotavirus vaccine, pneumococcal vaccines, and injectable and monovalent oral polio vaccines [3].

The combined vaccines are costlier than single vaccines and they almost never have more efficacy than single vaccines [4]. In India a major flaw is in the approach to vaccines, which most of the time is "vaccine-targeted" and not "disease-targeted". This flaw is more glaring at a time of resource scarcity when our government is spending merely one per cent of its gross domestic product on health [5].

### Hepatitis B Vaccine

The hepatitis B virus (HBV) is transmitted by percutaneous and per mucosal exposure to infected blood and other body fluids, mainly semen and vaginal fluid [5]. The WHO guidelines state that countries with less than 2% prevalence of chronic hepatitis B infection can take up a "selective" vaccination programme [6]. The WHO dropped this condition in recent years to favour the introduction of new vaccines [5,7].

The vaccine is 95% effective in preventing infection and the development of chronic disease and liver cancer due to hepatitis B. The majority of hepatitis B carriers go through life unaware of the presence of hepatitis B surface antigens in their body and unaffected by it and annually, 10% of the carriers become sero negative [7,8]. Hepatocellular carcinoma, the major HBV related cause of

death, is rare in India and constitutes only 1.6% of all cancers. The estimated annual deaths attributable to hepatocellular carcinoma due to hepatitis B are approximately 5,000 [9]. It is to be administered to adults who have a specific risk, or lack a risk factor but want protection, 3-dose series of single antigen hepatitis B vaccine (HepB) or combined hepatitis A and hepatitis B vaccine (HepA-HepB) at 0, 1, and 6 months (minimum intervals: 4 weeks between doses 1 and 2 for HepB and HepA-HepB; between doses 2 and 3, 8 weeks for Hep B and 5 months for Hep A-HepB).

To prevent transmission of hepatitis from mother to child, the vaccine should be given as soon as possible, ideally within 24 hours of birth [9]. Since 70% of carriers are infected in adulthood, immunisation at birth is not crucial [9].

The cost of vaccinating 25 million newborns every year is Rs 250 crore: double the budget for control of tuberculosis which kills 5 lakh Indians every year and more than the cost of all other six vaccines being given to children under the National Immunization Programme [10]. Instead of universal coverage only newborn babies whose mothers are carriers of hepatitis B should get this vaccine selectively within 48 hours (in Indian conditions) of birth, as this infection is passed on to them during birth. The IAP schedule is three doses at 0, six and 14 weeks [4]. The current UIP schedule recommends a four-dose schedule of the Hepatitis B vaccine, at 0, six, 10 and 14 weeks. In a country like India where less than 40% of mothers deliver in healthcare institutions [11], the extra dose at 10 weeks can be viewed as a luxury and an unrealistic addition to the programme. Considering the low prevalence of Hepatitis B, and the resource constraints, this vaccine should be limited to babies born to Hepatitis B positive mothers [12].

### Haemophilus B Influenza

Natural immunity due to infections with cross-reacting bacteria may explain the low incidence of invasive Hib disease in India and the reason why this population does not need vaccination with Hib [13]. Besides, the cost of the vaccine is so high to that it is not realistic to recommend it in UIP [14].

Minimum age for Haemophilus influenzae type b (Hib) vaccine is 6 weeks. Routine vaccination is done with Act HIB, Hiberix, or Pentacel in a 4-dose series at 2, 4, 6, and 12–15 months and with Pedvax HIB in 3-dose series at 2, 4, and 12–15 months. Catch-up vaccination with 1st dose at 7–11 months is followed by 2nd dose at least 4 weeks

later and 3rd (final) dose at 12–15 months or 8 weeks after 2nd dose (whichever is later).

### Pneumococci

Transient nasopharyngeal colonisation, and not the disease itself, is the normal outcome of exposure to Pneumococci [15]. Middle-ear infections, sinusitis and bronchitis represent the more common non-invasive and less severe manifestations of pneumococcal infection. PCV-7, which is currently the only commercially available pneumococcal conjugate vaccine, is licensed in more than 70 countries. The primary dose of PCV-7 consists of three intramuscular doses administered to infants at intervals of at least four weeks, starting at the age of six weeks or later [15]. Use in children aged less than five years provides protection for a duration of two to three years [15]. The Indian serotypes 1 and 5 account for about 29% of pneumococcal disease in India and the PCV-7. The vaccine does not contain antigens against these serotypes [4].

Poor nations will need to assess its cost utility carefully [16]. It is feared that for every four children in whom pneumonia is prevented, two children develop asthma because of the vaccine which will have far reaching negative influence on the lives of millions of children all over the world.

1 dose of 13-valent pneumococcal conjugate vaccine administered to immunocompetent adults aged 65 years or older (PCV13), if not previously administered, followed by 1 dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23) at least 1 year after PCV13.

### Rubella

Rubella is a common cause of maculopapular rash illness with fever. The disease has minor complications unless it is contracted in the first trimester of pregnancy [17]. Natural rubella infection normally confers lifelong immunity [18]. In India about 50% of children acquire rubella antibodies by the age of five years and 80-90% become immune by the age of 15 [19].

Women acquiring rubella in the first trimester of pregnancy can pass the infection to the fetus, resulting in the newborn being born with congenital rubella syndrome (CRS). Rubella vaccination is mainly to prevent CRS and not to prevent benign rubella infection [4]. WHO recommends prevention of CRS through immunisation of adolescent girls and/or women of childbearing age and elimination of rubella as well as CRS through universal

vaccination of infants, surveillance and assuring immunity in women of childbearing age [18].

MMR vaccines have saved 20 million lives globally since 2000. Rubella or MMR vaccine should not be introduced through public health facilities where immunization coverage is consistently less than 80% [4]. In India the measles vaccine is already given in the UIP at the age of 9-12 months and the combined mumps-measles rubella (MMR) vaccine is given at the age of 15 months.

### Varicella Vaccination

2 doses of varicella vaccine (VAR) 4–8 weeks apart are given if one has previously received no varicella-containing vaccine. Pregnant women in whom there is no evidence of immunity first of the 2 doses or the second dose is given after pregnancy and before discharge from health care facility [20]. Deaths due to Varicella declined by 87% during 2008 to 2011 as compared to 1990 to 1994 based on data from the National Center for Health Statistics (NCHS) following use of varicella vaccine.

### Zoster Vaccination

2 doses of recombinant zoster vaccine (RZV) are administered 2–6 months apart to adults aged 50 years or older regardless of past episode of herpes zoster or receipt of zoster vaccine live (ZVL). 2 doses of RZV 2–6 months apart to adults who previously received ZVL at least 2 months after ZVL. For adults aged 60 years or older, RZV is preferred. ZVL is contraindicated for pregnant women and adults with severe immunodeficiency [21].

### Human Papillomavirus Vaccination

Human papillomavirus vaccination is given to females through age 26 years and males through age 21 years. The number of doses of HPV vaccine to be administered depends on age at initial HPV vaccination. With no previous dose of HPV vaccine 3-dose series is administered at 0, 1–2, and 6 months (minimum intervals: 4 weeks between doses 1 and 2, 12 weeks between doses 2 and 3, and 5 months between doses 1 and 3).

In 9-14 years at HPV vaccine series initiation and who received 1 dose or 2 doses less than 5 months apart 1 dose is administered. If aged 9-14 years at HPV vaccine series initiation and received 2 doses at least 5 months apart no additional dose is needed [22].

It is not recommended during pregnancy, but there is no evidence that the vaccine is harmful and no intervention needed for women who inadvertently receive HPV vaccine while pregnant; remaining doses are delayed until after pregnancy.

### Hepatitis A Vaccination

Administered to adults who have a specific risk, or lack a risk factor but want protection, 2-dose series of single antigen hepatitis A vaccine (HepA; Havrix at 0 and 6–12 months or Vaqta at 0 and 6–18 months; minimum interval: 6 months) or a 3-dose series of combined hepatitis A and hepatitis B vaccine (HepA-HepB) at 0, 1, and 6 months; minimum intervals: 4 weeks between first and second doses, 5 months between second and third doses.

Healthy adults through age 40 years who have recently been exposed to hepatitis A virus and adults older than age 40 years may receive HepA or HepA-HepB if hepatitis A immunoglobulin cannot be obtained [23].

### Rotavirus Vaccines

Rotavirus vaccine is most effective in high-income countries, preventing approximately 71% of rotavirus deaths and 26% of diarrheal deaths. Minimum age for vaccine administration is 6 weeks. Routine vaccination is with Rotarix i.e. 2-dose series at 2 and 4 months and RotaTeq which is 3-dose series at 2, 4, and 6 months. The maximum age for the final dose is 8 months [24].

### Diphtheria, Tetanus, and acellular Pertussis (DTaP) Vaccine

Minimum age is 6 weeks. Routine vaccination is a 5-dose series at 2, 4, 6, and 15–18 months, and 4–6 years. Prospectively a 4th dose may be given as early as age 12 months if at least 6 months have elapsed since the 3rd dose. Retrospectively a 4th dose that was inadvertently given as early as 12 months may be counted if at least 4 months have elapsed since the 3rd dose.

In Catch-up vaccination the 5th dose is not necessary if the 4th dose was administered at 4 years or older [25].

### Inactivated Poliovirus Vaccine (IPV)

Routine vaccination consists of 4-dose series at ages 2, 4, 6-18 months, and 4-6 years. The final dose is administered on or after the 4th birthday and at least 6 months after the previous dose. For catch-up vaccination

1 more dose is given at age 4-6 years and at least 6 months after the previous dose if 4 or more doses were given before the 4th birthday. A 4th dose is not necessary if the 3rd dose was given on or after the 4th birthday and at least 6 months after the previous dose [26].

### Conclusion

The introduction of newer vaccines have often resulted in increased access to new and old vaccines in most documented cases which has resulted in necessary changes in the health and medical management practices. Awareness and demand for immunization has also been increased. India must evolve its own national strategies to meet its vaccination needs within its budgetary constraints. Access to certain special groups is increasing in certain settings and the development of integrated programmes has increased utilization of other health services. The spill-over effects on the routine immunization system and other health system sectors that is increased uptake, better timeliness in service delivery, greater cost-effectiveness, improved safety practices and reduction in wastage still needs to be examined.

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