

*Partha's*  
**IMMUNIZATION DIGEST**

5



# *Partha's* **IMMUNIZATION DIGEST**

**THIRD EDITION**

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***Dedicated to***

*The underprivileged children who miss the opportunity of routine immunization and need special campaigns for catch-up immunization*

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## FOREWORD

I am delighted to know that *Partha's Immunization Digest*, the popular handbook on vaccines and immunization practices, written by my close friend Professor A. Parthasarathy is due for its 3rd edition, and this time in association with Dr Alok Gupta of Jaipur, Rajasthan, India. Both veterans have worked hard to update the text with latest information on immunization.

The Internet Era has revolutionized the knowledge, attitude and practice (KAP) on immunization of both parents as well as doctors. Day-in and day-out new information keeps on pouring in. So much so, the medical practitioner is in a dilemma as to which vaccine to prefer and how to schedule it.

Numerous guidebooks published on behalf of the Indian Academy of Pediatrics and by private authors are available. A worthy addition to the existing collection has now come in the form of this manual entitled *Partha's Immunization Digest*. The authors have taken pains to collect available useful literature on immunization both from Indian and foreign sources and presented the resume in a reader-friendly yet concise and informative manner. The text on development of various types of vaccine formulations is highly informative as also the text on future vaccines.

I compliment them for their laudable effort and hope the new manual will be welcomed by all those concerned with infant, child and adolescent immunization. I am happy to learn that the book is now being published in revised version which speaks of its popularity. I am sure the revised version with updated information will benefit the readers to update their knowledge on changing concepts in immunization. I can say without hesitation that this is perhaps the one and the only digest of its kind available in Indian market, which incorporates concise yet latest precise information on all aspects of globally available vaccines and immunization practices.

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## PREFACE TO THE THIRD EDITION

Immunization of children, adolescents and adults is a fascinating field of medical practice, which needs to be updated with latest information periodically. The reception by practitioners of immunization for the first two editions of this tiny yet informative booklet prompted the authors to revise and update the last edition with latest information on current developments in immunization practices.

With this objective, the book has been revised by incorporating guidelines from the World Health Organization, UNICEF, Government of India, American Academy of Pediatrics, and Indian Academy of Pediatrics. When the authors visited the various immunization websites and accessed the recommendations of WHO, UNICEF, Government of India, AAP and IAP, the information was enormous. To collect such latest information and present them in a concise format is an uphill task.

We have tried our best to present the current information in a reader-friendly and easy-to-refer format in this small digest. The twin objectives of any immunization program/practice are: (i) protection of the individual vaccinee against the targeted vaccine preventable disease (VPD) and (ii) to control, eliminate and eradicate the targeted VPD at the community level. This small booklet is dedicated to achieve these two objectives and to strengthen the private-public partnership in the field of immunization activities, thus, bridging the benefits of immunization carried out in office practice with the public health program of the governments.

Your valuable suggestions are welcomed to improve the contents of the book in its future editions.

**A Parthasarathy  
Alok Gupta**

Jaypee Brothers

## PREFACE TO THE FIRST EDITION

Immunization has been regarded as the greatest success story of 20th century. With effective immunization of newborns, infants, children and adolescents, global eradication of smallpox was achieved in 1978. Similarly, poliomyelitis has since been eradicated in developed countries; controlled in many countries and is in the process of elimination in developing countries, at the global scenario. Nevertheless, emerging and re-emerging infections are still posing a challenge.

Advances in molecular biology and genetic engineering are revitalizing the concept of immunization. Novel vaccine delivery systems have been developed. Auto-destruct/self-locking syringes have promoted the *Needle smart* message. Knowledge, attitude and practice (KAP) on immunization for doctors and parents have been enriched through continuing medical education (CME) of vaccine updates and parent health education, and through the vigorous media advertisements of the vaccine manufactures. Due to these awareness campaigns, demand generation has increased. Newer vaccines are being licensed in India, after their efficacies have been established at the global level.

In addition to the vaccines administered in the National Immunization Schedule, it has become necessary to recommend additional vaccines at different age groups. Apart from newborn, infant and childhood immunization practices, immunization of adolescents has also become a campaign by itself. In this manual, attempt has been made to present a *state-of-the art* information concerning issues related to vaccines and immunization. Existing *state-of-the art* tables and text of international and national authors have been included with necessary modifications with due acknowledgment. Hope, the new venture will be welcomed by practising pediatricians and family physicians. Your comments and suggestion are most welcomed to improve the quality of future editions.

**A Parthasarathy**



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## Immunization in Special Clinical Circumstances

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Certain immunizations are mandatory in special clinical circumstances. The following resume gives an account of the same.

### **IMMUNIZATIONS REQUIRED OR RECOMMENDED BECAUSE OF RISK OF DISEASES**

#### **Preterm Infants Born to Mothers Not Tested During Pregnancy for HBsAg**

The maternal HBsAg status should be determined as soon as possible, and the infant should receive hepatitis B vaccine, as recommended for term infants in this category. For preterm infants who weigh less than 2 kg at birth, HBIG (0.5 mL) should be given if the mother's HBsAg status cannot be determined within the initial 12 hours of birth because of the poor immunogenicity of vaccine in these infants. The initial vaccine dose should not be counted in the required 3 doses to complete the immunization series. The subsequent 3 doses (or a total of 4 doses) are given in accordance with the recommendations for the immunization of preterm infants with birth weights less than 2 kg born to HBsAg-negative women.

## RECOMMENDED SCHEDULE OF HEPATITIS B IMMUNOPROPHYLAXIS TO PREVENT PERINATAL TRANSMISSION (TABLE 5.1)

**Table 5.1:** Hepatitis vaccination schedule

<i>HB vaccine and HBIG dose</i>	<i>Age</i>
<b>Infant born to mother known to be HBsAg positive</b>	
First dose of hepatitis B vaccine	Birth (within 12 hours)
HBIG	Birth (within 12 hours)
Second dose of hepatitis B vaccine	6 weeks
Third dose of hepatitis B vaccine	14 weeks/24 weeks
Final dose of hepatitis B vaccine (3rd or 4th)	24 weeks (6 months)
<b>Infant born to mothers not screened for HBsAg</b>	
First dose of hepatitis B vaccine	Birth (within 12 hours)
HBIG	If mother is HBsAg-positive, give 0.5 mL, as soon as possible, not later than 1 week after birth
Second dose of hepatitis B vaccine	6 weeks
Third dose of hepatitis B vaccine	14 weeks/24 weeks
Final dose of hepatitis B vaccine (3rd or 4th)	24 weeks (6 months)

HBsAg indicates hepatitis B surface antigen; HBIG, hepatitis B immunoglobulin.

HBIG (0.5 mL) given intramuscularly at a site different from that used for vaccine.

### Breastfeeding

Breastfeeding of the infant by an HBsAg-positive mother poses no additional risk for acquisition of HBV infection by the infants by human milk.

### Household Contacts of Persons with Acute HBV Infection

Infants (i.e. younger than 12 months of age) who have close contact with primary caregivers with acute infection and who have begun the immunization series should complete the series on schedule. If immunization has not been initiated, the infant should receive HBIG (0.5 mL), and hepatitis vaccine should be given in accordance with the routinely recommended 3-doses schedule (see Pre-exposure Universal Immunization).

## RECOMMENDATIONS FOR POSTEXPOSURE IMMUNE PROPHYLAXIS OF HEPATITIS A INFECTION (TABLE 5.2)

**Table 5.2:** Post-exposure Immune prophylaxis of Hepatitis A Infection

<i>Time since exposure, week</i>	<i>Future exposure likely, or immunization</i>	<i>Age of patients</i>	<i>Recommended prophylaxis</i>
≤2 week	No Yes	Younger than 12 months 12 months through 40 years 41 years or older	IGIM (0.02 mL/kg) * IG (0.02 mL/kg) * and hepatitis A vaccine IGIM 0.02 mL/kg*HEPA vaccine <sup>^</sup> can be used if IGIM unavailable*
>2 week	No Yes	Younger than 12 months 12 months or older No prophylaxis but hepatitis A vaccine may be indicated for ongoing exposure <sup>^</sup>	No prophylaxis Hepatitis A vaccine

**Abbreviations:** IGIM, Immunoglobulin intramuscular.

\*IGIM should be administered deep into a large muscle mass. Ordinarily no more than 5 mL should be administered in one site in an adult or large child; lesser amounts (maximum, 3 mL) should be given to small children and infants.

<sup>^</sup> Dosage and schedule of hepatitis A vaccine as recommended as per age.

\* Source: Red Book 2015 pp 386-8, 30th ed. American Academy of Pediatrics.

## RECOMMENDED IMMUNIZATION SCHEDULES FOR CHILDREN NOT IMMUNIZED IN THE FIRST YEAR OF LIFE (TABLE 5.3)

**Table 5.3:** Immunization Schedules for Children Not Immunized in the First Year of Life

<i>Recommended time/age</i>	<i>Immunization</i>	<i>Comments</i>
1. Younger than 5 years: First Visit	BCG, IPV <sup>1</sup> /OPV <sup>1</sup> , DPT <sub>1</sub> , HB <sub>1</sub> , Hib <sub>1</sub>	If indicated, tuberculin testing may be done at same visit. If child is 5 years of age or older, Hib is not indicated in most circumstances.
2nd visit (after 4 weeks' of above)	DTP <sub>2</sub> , IPV <sub>2</sub> /OPV <sub>2</sub> , HB <sub>2</sub> , Hib <sub>2</sub> , MMR <sub>1</sub>	

Contd...

Contd...

<i>Recommended time/age</i>	<i>Immunization</i>	<i>Comments</i>
3rd visit (after 4 weeks of above)	DTP <sub>3</sub> , IPV <sub>3</sub> /OPV <sub>3</sub> , HB <sub>3</sub> , Hib <sub>3</sub> , MMR <sub>2</sub>	
2. Age 5 years and above (at or before school entry)	Hepatitis B 3 doses at 0, 1 and 6 months, Td 3 doses at 4 weeks' interval, Varicella 2 doses preferably at 3 months' interval, MMR 2 doses at minimum 4 weeks' interval	
3. Age 10 years and above	Hepatitis A (inactivated) 2 doses at 0 and 6 months. Varicella 2 doses preferably at 3 months' interval	
4. Age 16 years and above	Hepatitis B 3 doses at 0, 1 and 6 months, Tdap single dose, Hepatitis A 2 doses at 0 and 6 months, Varicella 2 doses at 4 weeks', MMR 2 doses at minimum 4 weeks' interval	

- Note:**
- Table is not completely consistent with all package inserts. For products used, also consult manufacturer's package insert for instruction on storage, handling, dosage, and administration. Biologicals prepared by different manufacturers may vary and package inserts of the same manufacturer may change. Therefore, the physician should be aware of the contents of the current package insert. Vaccine abbreviations: HB indicates hepatitis B virus; Var, varicella; DTP, diphtheria and tetanus toxoids and whole cell pertussis; Hib, Hemophilus influenza type b conjugate; IPV, inactivated polio vaccine, OPV, live poliovirus, MMR, live measles-mumps-rubella; Td, adult tetanus toxoid (full dose) with reduced dose of diphtheria toxoid.
  - If all needed vaccines cannot be administered simultaneously, priority should be given to protecting the child against the diseases that pose the greatest immediate risk. In the United States, these diseases for children younger than 2 years usually are measles and Hemophilus influenza type infection, for children older than 7 years, they are measles, mumps, and rubella. Before 13 years of age, immunity against hepatitis B and varicella should be ensured. DTPa, HBV, Hib MMR and varicella can be given simultaneously at separate sites if failure of the patient to return for future immunizations is a concern.
  - Varicella vaccine can be administered to susceptible children any time after 15 months of age. Unimmunized children who lack a reliable history of varicella should be immunized before their 13th birthday.
  - Minimal interval between two doses of MMR is 1 month (4 weeks).
  - HBV may be given in a 3-dose schedule with minimum 4 weeks interval, ideal being 0-1-6-month schedule.



## **SIMULTANEOUS ADMINISTRATION OF MULTIPLE VACCINES**

Most vaccines can be safely and effectively administered simultaneously. No contraindication is known to the simultaneous administration of multiple vaccines routinely recommended for infants and children. Immune responses to one vaccine generally do not interfere with those to other vaccines; concerns include interference among the 3 oral poliovirus serotypes in trivalent OPV vaccine and concurrent administration of measles and MMR vaccines. Simultaneous administration of OPV, MMR, varicella, or DTP vaccines has resulted in similar rates of sero conversion and of side effects like those observed when the vaccines are administered at separate times. Because simultaneous administration of common vaccines is not known to affect the efficacy or safety of any of the routinely recommended childhood vaccines, simultaneous administration of all vaccines (DTP, OPV, MMR, varicella, hepatitis B, and Hib vaccines) appropriate for the age and previous immunization status of the recipient is recommended. Simultaneous administration of multiple vaccines can raise immunization rates significantly.

For persons preparing for foreign travel, multiple vaccines generally can be given concurrently. An exception is the simultaneous administration of yellow fever and cholera vaccines. Antibody responses to both cholera and yellow fever vaccines are decreased if given simultaneously or within a short time of each other. If possible, these vaccines should be separated by at least 3 weeks; alternatively, cholera vaccine could be omitted since its effectiveness is limited and few indications for its use exists.

If both vaccines are necessary and time constraints exist, these vaccines can be given simultaneously or within a 3 week period with the understanding that antibody responses may not be optimal.

When vaccines commonly associated with substantial local or systemic reactions, e.g. cholera, parenteral typhoid vaccines and plague are given simultaneously, the reactions can be accentuated. Thus, in most circumstances, if feasible, these vaccines should be given on separate occasions.

MMR and TCV vaccines should be separated by an interval of 4 weeks pending studies of concurrent administration.

## **LAPSED IMMUNIZATIONS**

A lapse in the immunization schedule does not require reinstating of the entire series. If a dose of DTP, OPV, Hib or hepatitis B vaccine is missed, immunizations should be given at the next visit as if the usual interval had elapsed. The medical charts of children in whom immunizations have been missed or postponed should be flagged to remind health care professionals to complete immunization schedules at the next available opportunity. If status is unknown, consider them as unimmunized and administer age-appropriate vaccine at recommended schedule.

## **UNKNOWN OR UNCERTAIN IMMUNIZATION STATUS**

A physician may encounter some children with an uncertain immunization status. Many young adults and some children do not have adequate documentation of immunizations and recollection by the parent or guardian may be of questionable validity. In general, these persons should be considered disease susceptible and age-appropriate immunizations should be administered. No evidence indicates that administration of MMR, varicella, Hib, hepatitis B, or poliovirus vaccine to already immune recipients is harmful.

## **ACTIVE IMMUNIZATION OF PERSONS WHO RECENTLY RECEIVED IMMUNOGLOBULIN**

Live-virus vaccine given parenterally can have diminished immunogenicity when given shortly before or during a period of several months after receipt of immunoglobulins. High doses of immunoglobulin have been demonstrated to inhibit the response to measles vaccine for a prolonged period. The duration of inhibition varies directly with the dose of immunoglobulin administered. Inhibition of immune response to rubella, while of shorter duration than

measles, also has been demonstrated. The appropriate suggested interval between immunoglobulin administration and measles immunization will vary with the indication for immunoglobulin (which determines the dose) and specific product, e.g. immune globulin vs immunoglobulin intravenous. If immunoglobulin must be given within 14 days after administrations of measles or measles-containing vaccines, these live-virus vaccines should be administered again after the period specified unless serologic testing at an appropriate interval after immunoglobulin administration indicates that adequate serum antibodies were produced.

The effect of administration of immunoglobulin on the antibody response to varicella vaccine is not known. Because of potential inhibition of the response, varicella vaccine should not be administered after receipt of an immunoglobulin preparation or a blood product (except washed red blood cells), as recommended for measles vaccine. In addition, immune globulin preparations, if possible, should not be administered for 14 days' after immunization. If an immune globulin preparation is given in this interval, the vaccine recipient should be reimmunized after the period or tested for varicella immunity at that time and reimmunized if seronegative.

In contrast with live-virus vaccines given parenterally, administration of immune globulin preparations has not been demonstrated to cause significant inhibition of the immune responses to inactivated vaccines and toxoids. For example, concurrent administration of recommended doses of hepatitis B immunoglobulin, tetanus immunoglobulin, or RIG and the corresponding inactivated vaccine or toxoid indicate long-term immunity, i.e. active and passive immunoprophylaxis. Standard doses of the corresponding vaccines are recommended. Increases in the vaccine dose volume or number of immunizations are not indicated. Vaccines should be administered at sites different from that of intramuscularly administered immune globulin.

Administration of hepatitis A vaccine together with IG has been recommended for situations in which immediate and prolonged protection against HAV infection is desired. Although this combined active-passive immunization has been demonstrated to result in significantly lower serum

antibody concentrations than those induced by vaccine administration only, these concentrations are still many times higher than those considered protective and sero conversion rates are not affected. The reduced immunogenicity, therefore, is to be considered clinically significant.

Other than deferral of MMR and varicella vaccines, as previously discussed, these recipients should be immunized as per the recommended schedule for routine childhood immunization.

*Administration of immune globulin preparations does not interfere with antibody responses to yellow fever or OPV vaccines. Hence, OPV and yellow fever vaccines can be administered simultaneously with or at any time before or after immune globulin, such as to travellers whose departure is imminent.*

## **PREGNANCY**

TT/Td/Tdap and inactivated influenza can safely be given. Live virus vaccines are contraindicated in general. Hepatitis A, HB and pneumococcal vaccines can also be given. All vaccines except yellow fever vaccine are safe in lactating women. Rabies vaccination for postexposure prophylaxis is not contraindicated.

## **CHILDREN ON STEROIDS**

1. *Topical therapy or local injections of corticosteroids.* Administration of topical corticosteroids, either on the skin or in the respiratory tract (i.e., by aerosol) or eyes, and intra-articular, bursal, or tendon injections of corticosteroids usually do not result in immunosuppression that would contraindicate administration if clinical or laboratory evidence of systemic immunosuppression results after prolonged application until corticosteroid therapy has been discontinued for at least 1 month.
2. *Physiologic maintenance doses of corticosteroids.* Children who are receiving only maintenance physiologic doses of corticosteroids can receive live-virus vaccines during corticosteroid treatment.
3. *Low or moderate doses of systemic corticosteroids given daily or on alternate days.* Children receiving less than

2 mg/kg per day of prednisone or its equivalent, or less than 20 mg/d if they weigh more than 10 kg can receive live-virus vaccines during corticosteroid treatment.

4. *High doses of systemic corticosteroids given daily or on alternate days for fewer than 14 days.* Children receiving 2 mg/kg per day or more of prednisone or its equivalent, or 20 mg or more daily if they weigh more than 10 kg, can receive live-virus vaccines immediately after discontinuation of treatment. Some experts, however, would delay immunization until 2 weeks after corticosteroid therapy, if possible (i.e., provided the patient's condition allows temporary cessation).
5. *High doses of systemic corticosteroids given daily or on alternate days for fewer than 14 days or more.* Children receiving 2 mg/kg per day or more of prednisone or its equivalent, or 20 mg or more daily if they weigh more than 10 kg, should not receive live-virus vaccines until corticosteroid therapy has been discontinued for at least 1 month.
6. *Children with a disease that, in itself, is considered to suppress the immune response and who are receiving systemic or locally administered corticosteroids.* These children should not be given live-virus vaccines except in special circumstances.

## **HODGKIN'S DISEASE**

Children suffering from Hodgkin's disease should receive pneumococcal and Hib vaccines as per recommendations.

## **ASPLENIC CHILDREN (CONGENITAL ASPLENIA, SICKLE CELL DISEASE, SPLENECTOMY)**

Children with congenital asplenia or after splenectomy (functional asplenia) or sickle-cell disease should receive Hib as well as pneumococcal vaccines.

## **CHILDREN WITH HIV/AIDS**

In India, children with HIV AIDS should receive immunization as per the Table 5.1.

**Table 5.4:** Immunization of Indian children to prevent HIV, AIDS

<i>Vaccines</i>	<i>Known symptomatic HIV infection</i>	<i>Symptomatic HIV infection</i>
BCG	Yes	Yes*
Hepatitis B	Yes	Yes
DTP	Yes	Yes
OPV	Yes	Yes
MMR	Yes	Yes**
Hib	Yes	Yes
Pneumococcal	Yes	Yes
Influenzae	Yes	Yes
Hepatitis A	Consider	Consider
Varicella	Consider	Consider

\* Yes in India where TB is highly endemic

\*\* Severely immunocompromized HIV

\*\*\* Infected children should receive MMR, if available

## IMMUNIZATION IN BLEEDING DISORDERS

Subcutaneous route preferred unless contraindicated. Aluminium salt adjuvanted vaccines can be given IM with caution by applying deep pressure after vaccination at the injection site. It is ideal to immunize after factor replacement therapy. Facilities for immediate blood transfusion should be available if uncontrolled bleeding occurs at injection site. Always immunize these children in a hospital set up.

## IMMUNIZATION IN CHILDREN WITH HISTORY OF ALLERGY

If previous history of hypersensitivity/anaphylaxis is to any vaccine is present, do not use the same vaccine again. If history of egg allergy is present, only influenza and yellow fever vaccines are contraindicated. Measles and MMR vaccines can be given as they are propagated in chick embryo cells only. If history of any hypersensitivity present, JE vaccination should be done cautiously, facilities for cardiopulmonary resuscitation (CPR) is mandatory.

## ORGAN TRANSPLANT INDIVIDUALS

All inactivated/subunit vaccines may be given safely to all transplant patients. In planned transplant, the donor may

be given the required vaccines. However, in bone marrow transplant patients, the entire age appropriate series should be restarted in view of marrow ablation.

## **VACCINATION OF THE INDIVIDUAL WITH CANCER/ CHEMOTHERAPY**

Vaccines indicated—Catch up DTPw/DTPa, hepatitis B, pneumococcal, varicella and MMR vaccines should be given before initiation of chemotherapy or 3–6 months after chemotherapy. All live vaccines should be avoided at least 3 months after chemotherapy or radiotherapy.

## **IMMUNIZATION IN RELATION TO ANTIBODY CONTAINING PRODUCTS**

Inactivated vaccines are safe. Live vaccines viz. MMR, varicella, etc. should be avoided for 3 months. Antibody containing products should be avoided at least for 2 weeks after these vaccinations. Oral typhoid vaccine, live attenuated influenza vaccine (LAIV) OPV and yellow fever vaccines may be given at any time indicated as for age. Rotavirus vaccines should be avoided for 6 weeks.

## **IMMUNIZATION FOR TRAVELERS**

Travellers to India should receive typhoid, HAV, HBV, varicella, rabies vaccines and JE vaccine if traveling to JE endemic areas during JE session. Traveller from India if traveling to South Africa, sub-Saharan should receive yellow fever vaccine. If on Haj pilgrimage, polio and meningococcal vaccines are indicated. Travelers to Africa should receive Meningococcal vaccine in addition to yellow fever vaccine.

## **LEARNING POINTS**

- Specific vaccines recommended by professional bodies should be administered to children and adolescents at appropriate ages and situations
- Each country specifies travel-related vaccines to be taken for those visiting the country and for students proceeding abroad for higher studies
- For Haj pilgrims' Meningococcal vaccination is mandatory.

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