2nd Edition

Immunization in Clinical Practice

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Immunization Schedules

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INTRODUCTION

Immunization is one of the most cost-effective health interventions known to mankind. It is also true that immunization is the most successful, single, child survival strategy to date. Immunization schedules are the basic framework for the delivery of vaccines to individuals as well as the community as a whole. No single schedule is applicable to all countries or the communities of the world, as immunization schedule has to be framed according to the needs of the individual situation. Therefore, immunization schedule will vary from country to country and from time to time. Thus, there are numbers of immunization schedules, each one having its own advantages and disadvantages. A well-planned immunization schedule should be epidemiologically relevant, immunologically competent, technically feasible, economically viable and socioculturally acceptable.

Many factors are considered while preparing the recommendations and schedules for successful vaccination program in the country. These include epidemiology of the disease, age-specific morbidity and mortality, vaccine immunogenicity, efficacy and effectiveness, risks of vaccine-related adverse reactions, cost effectiveness, health service infrastructure, etc. In order to choose vaccines for vaccination program at government funding, not only disease burden but their implications should also be known. For government programs, usually it is cost first, efficacy next and safety last. For an individual, it is safety first, efficacy next and cost last. Though what is not in the best interest of the individual cannot be in the best interest of community and what is in the best interest of the community is also in the best interest of the individual. In the past two decades, many new vaccines have developed, vaccine schedule is undergoing rapid changes and has become more complex. It often becomes a matter of debate what is the best schedule, but the knowledge of principles that go behind making each schedule will help pediatricians to build an informed opinion.

PRINCIPLES OF VACCINE SCHEDULING

Vaccines are recommended for individuals of the youngest age group at risk of experiencing the disease. Optimal response to a vaccine depends upon multiple factors. These include the following.

NATURE OF VACCINE

Vaccines consist of whole inactivated microorganisms [e.g. injectable polio vaccine (IPV), hepatitis A], parts of organisms (e.g. acellular

pertussis, human papilloma virus (HPV), hepatitis B virus (HBV), polysaccharide capsules (e.g. pneumococcal and meningococcal polysaccharide vaccines), polysaccharide capsules conjugated to protein carrier [e.g. *Haemophilus influenzae* type b (Hib), pneumococcal and meningococcal conjugate vaccines], live attenuated microorganisms (measles, mumps, rubella, varicella, oral polio vaccine (OPV), rotavirus and live influenza vaccines) and toxoids (tetanus, diphtheria). Attenuated vaccines are prepared by nullifying or minimizing pathogenicity (capacity of producing disease) of the organism and maintaining or enhancing its immunogenicity (capacity of producing antibodies).

Certain vaccines (inactivated vaccines, toxoids, recombinant subunit and polysaccharide conjugate vaccines) require administration of more than two doses for development of an adequate and persisting antibody response. Toxoids (tetanus and diphtheria) require periodic reinforcement or booster dose to maintain protective antibody concentrations. Unconjugated polysaccharide vaccines do not induce T cell memory and hence repeated doses do not produce substantial boosting. However, when conjugated with a protein carrier, the effectiveness of polysaccharide vaccines improves by inducing T cell-dependent immunity. Live attenuated virus vaccines stimulate both cell mediated as well as humoral immunity and, hence, usually can induce prolonged, often lifelong immunity, even if antibody titers decline as time progresses. Subsequent exposure to infection leads to a rapid anamnestic antibody response.

IMMUNOGENICITY AND POTENTIAL INTERFERENCE BY PASSIVELY TRANSFERRED MATERNAL ANTIBODIES

The timing of the first immunization is a compromise between the developing immunity by the infant's immune system and the risk of infection. Maternal transplacental IgG antibodies are protective for the first few months of life. In early infancy, the protection is partial for some diseases, such as pertussis, and satisfactory against others such as measles. The production of a satisfactory primary antigen response is vital, unless this is achieved, subsequent vaccines will not produce adequate recall response for effective protection.

The immune response of the vaccine is mediated by either humoral or cell-mediated immunity (CMI) or both. Some of the vaccines can stimulate immune system and can protect the child, which is the important factor for consideration while preparing the immunization schedule. Bacillus Calmette–Guerin (BCG), oral polio vaccine (OPV) and hepatitis B virus (HBV) vaccines can be given at birth. The BCG elicits a CMI and maternal antibodies do not interfere with CMI. Maternal antibodies present in baby against OPV have weak inhibitory effect and, therefore, OPV can establish local gut infection in a significant proportion of recipients. HBV is strongly immunogenic and can overcome the effect of maternal antibodies. Live measles and measles, mumps, and rubella (MMR) vaccines are inhibited by maternal antibodies till the age of 9 to 12 months.

LOCAL EPIDEMIOLOGY OF THE DISEASE

The optimal age for starting immunization depends upon both immunological maturity and local disease epidemiology. In countries like India, where tuberculosis and poliomyelitis may affect young children, immunization should be started soon after birth. In countries where pertussis is still common, the vaccine as diphtheria, pertussis, and tetanus (DPT) should be given in early infancy since pertussis in young infants has greater morbidity and mortality. When measles is a great threat, vaccine should be given early, despite the compromised response to it. In developed countries, measles vaccination may be deferred till the age of 12 to 15 months, since chances of early infection are less and the measles vaccine offers optimal response after the age of

12 months. In developing countries like ours, the World Health Organization (WHO) recommends measles vaccine between 9 and 12 months. It may be given earliest at the age of 6 months in high-risk situations. In addition to the WHO schedule, other available vaccines are recommended in specific regions, for example, Japanese encephalitis vaccine in hyperendemic areas.

Once any vaccine is available, before recommending it for a specific region or country, the disease epidemiology is studied. Once it shows existence of disease in community and significant disease burden, it is recommended for routine vaccination.

CHANGING EPIDEMIOLOGY OF THE DISEASE

With effective vaccination program and good coverage of vaccination in the community, there is a shift of the disease to the right in the age group affected by some vaccine preventable diseases. It has been observed in our country that now measles is affecting older children, chickenpox is also seen in adolescents and adults with life-threatening central nervous system (CNS) complications and whooping cough is seen in adults too. These changes indicate modifications in immunization schedules, extending age of vaccination in older children and even in adults.

SPACING OF MULTIPLE DOSES OF THE SAME ANTIGEN

Studies have shown that the recommended age of starting and the interval between doses of multidose antigens provide optimal protection or have the best evidence of efficacy. Vaccine doses should not be administered at intervals less than the minimum intervals or earlier than the minimum age. If vaccine doses are administered at interval less than the minimum interval or at younger age than the minimum age, a suboptimal immune response can ensue. However, administering a dose, a limited number of days earlier than the minimum interval or age is unlikely to have a substantially negative effect on the immune response to the dose. Therefore, it is recommended that vaccine dose administered <4 days before the minimum interval can be counted as valid, the only exception being the rabies vaccine.

There should be a minimum interval of 4 weeks between 2 doses of the same vaccine or between two different vaccines for optimum immunological response. In fact, increasing the interval of 8 weeks increases the concentration of antibody. However, due to some logistic reasons and to complete the immunization before the vulnerable age of the child for the disease, most of our immunization schedules are with interval of 4 weeks duration.

SIMULTANEOUS ADMINISTRATION OF VACCINES

The current vaccines which are used in children do not have significant interference with each other and hence several antigens can be given simultaneously. Simultaneous administration of all vaccines for which a child is eligible increases the probability that child will be fully immunized at appropriate age, as administering antigens at different times would result in a delay in protection for the deferred components. The simultaneous administration of live and inactivated vaccines have similar seroconversion rates as observed when they are administered at different times. Routinely, simultaneous administration of all vaccines is recommended for children who are of the appropriate age to receive them and for whom no specific contraindications exist at the time of visit.

COMBINATION VACCINES

The use of combination vaccines can reduce the number of pricks required at a single visit. The use of licensed combination vaccines is preferred over separate injections of their equivalent component vaccines.

VACCINE FAILURE

About 95% of recipients of a single dose of MMR vaccine develop protective antibody within 2 weeks of the dose. However, 5% of recipients, fail to respond to single dose and hence a second dose is recommended, since majority of vaccines exhibiting primary vaccine failure respond to the second dose. Similarly, a second dose of varicella is recommended at 4 to 6 years of age with the first dose at the age of 12 to 15 months of age to prevent breakthrough varicella. It is not clear whether breakthrough varicella occurs due to primary vaccine failure or due to waning immunity.

DEVELOPING AND DEVELOPED COUNTRIES

In developing countries like ours, booster immunization schedules present financial and logistic problems, so the main emphasis is on primary immunization as a part of basic health care. In India, injectable polio vaccine is yet to be incorporated in the national immunization schedule due to such reasons. Recently, Hepatitis B and Hib vaccines are included in our national immunization schedule.

UPDATING THE SUBJECT

A simple immunization schedule should be used. The frequent changes are not desirable. The guidelines should be available for staff and a simplified version for parents. All those involved in immunization program should be trained and new information should be disseminated quickly. The practical issues of the staff and parents should be solved immediately. The publications in question-answer format are more useful and easily accepted by the people.

PRACTICAL TRAINING

Practical training is very useful for successful immunization program. The people involved in immunization should be trained for practical aspects such as scientific information regarding the vaccines, care of vaccines, correct administration of vaccines, maintenance of equipment, and cold chain. They should be trained how to prepare and conduct an immunization session or immunization clinic. Periodic evaluation of an immunization program at different levels is important.

WHO AND IMMUNIZATION PROGRAMS

- Expanded Program of Immunization (EPI) was launched by the WHO in 1974 with the goal of reducing morbidity and mortality from six target diseases (tuberculosis, poliomyelitis, diphtheria, pertussis, tetanus and measles) by providing immunization services to all children less than 5 years old and pregnant women. The vaccines included were BCG, DPT, OPV, measles and TT.
- Universal Childhood Immunization (UCI) was adopted by the WHO. This program became universal instead of earlier target of 85% coverage of immunization as in the EPI. Special efforts were made to initiate research for understanding the epidemiology of the disease, development of newer vaccines and vaccine production technology.
- Child Vaccine Initiative (CVI) was implemented in 1991 after a summit for children in Washington DC in 1990. In the summit, the success of EPI was commemorated in achieving a global coverage of 80% with the six vaccines, and the achievement of UCI was highlighted. The aim was to enhance protection of children against all preventable infectious diseases by promoting newer vaccines and vaccine production technology.
- Global Program on Vaccination (GPV) was launched by the WHO in 1993. It was combination of EPI, UCI and CVI. Its main aims were eradication of polio, elimination of neonatal tetanus and prevention of mortality due to measles. **Table 3.1** shows the details of schedule advocated by the WHO.
- Global Alliance for Vaccines and Immunization (GAVI) replaced CVI in 1999. The

objectives of this program are improving access to sustainable immunization services, expanding the use of all existing safe and cost-effective vaccines, accelerating the development and introduction of new vaccines, accelerating research and development efforts for vaccines and related products and making immunization coverage a centerpiece in the design and assessment of international development efforts.

NATIONAL IMMUNIZATION SCHEDULE

- In India, EPI was launched in 1978 with the typhoid vaccine replacing measles.
- Unfortunately, the coverage of EPI was very low. In view of this, a revised strategy, Universal Immunization Program (UIP) was launched in 1985 to achieve target immunization goals in a phased and planned manner. The target was infants below 1 year of age, who were vaccinated against the target diseases as well as pregnant women who received TT. The aim was to achieve 100% coverage of all pregnant women and at least 85% of infants.

The immunization services were to be provided through the existing health care delivery system such as maternal and child health (MCH) centers, subcenters, primary health centers, dispensaries, hospitals, Integrated Child Development Services (ICDS) units, etc. It was further incorporated into the "Child Survival and Safe Motherhood (CSSM) in 1992 and the Reproductive and Child Health Program (RCH) in 1997.

This immunization schedule was devised taking into consideration the epidemiological profile of the childhood diseases which cause significant morbidity and mortality in India, as well as financial resources available, logistics, operational feasibility, availability and cost effectiveness of the vaccines. It has undergone time-to-time modifications as required. The latest one is given in **Table 3.1**

IAP IMMUNIZATION SCHEDULE

In view of data available on various vaccine preventable diseases and the availability of several vaccines, Advisory Committee on Vaccination and Immunization Practice (ACVIP) recommends the schedule as shown in **Tables 3.2** and **3.3**.

INTERNATIONAL IMMUNIZATION SCHEDULES

In the United States, recommendations for childhood immunization are formulated by two committees, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP) committee on infectious diseases. These two committees along with American Academy of Family Physicians issue an annual national schedule for routinely recommended childhood vaccinations **(Table 3.4)**. The immunization schedule currently being implemented in the United Kingdom is given in **Table 3.5**.

IMMUNIZATION IN ADOLESCENTS

Immune protection induced by vaccines given during infancy wanes over the years. It leads to higher incidence of vaccine preventable diseases in adolescents and adults with increasing risk of complications. Recently, vaccines have been modified and developed suitable for administering to adolescents offering protection against many diseases. IAP ACVIP recommends vaccines for adolescents as shown in **Tables 3.6** to **3.9**.

IMMUNIZATION SCHEDULE FOR AN UNIMMUNIZED CHILD

The immunization schedule for an unimmunized child depends upon the age of presentation. The reasons for child remaining unimmunized or partially immunized should be looked into and the parents should be counseled

Table 3.1 Vaccination schedule under Universal Immunization Program (UIP) in India, 2013

Vaccine	*When to give*	*Dose*	*Route*	*Site*
For pregnant women				
TT-1	Early in pregnancy	0.5 mL	Intramuscular	Upper arm
TT-2	4 weeks after TT-1*	0.5 mL	Intramuscular	Upper arm
TT- booster	If received 2 TT doses in a pregnancy within the last 3 years	0.5 mL	Intramuscular	Upper arm
For infants				
BCG	At birth or as early as possible till one year of age	0.1 mL (0.05 mL until 1 month of age)	Intradermal	Left upper arm
Hepatitis B birth dose	At birth or as early as possible within 24 hours	0.5 mL	Intramuscular	Anterolateral side of midthigh
OPV Zero dose	At birth or as early as possible within the 15 days	2 drops	Oral	Oral
OPV 1, 2 and 3	At 6, 10 and 14 weeks	2 drops	Oral	Oral
DPT 1, 2 and 3		0.5 mL	Intramuscular	Anterolateral side of midthigh
Hepatitis B 1, 2, and 3		0.5 mL	Intramuscular	Anterolateral side of midthigh
HIB 1, 2 and 3		0.5 mL	Intramuscular	Anterolateral side of midthigh
Measles 1st dose	9 completed months – 12 months (give up to 5 years if not received at 9–12 months age)	0.5 mL	Subcutaneous	Right upper arm
JE 1st dose**	9 completed months	0.5 mL	Subcutaneous	Left upper arm
For children and adolescents				
DPT booster	16–24 months	0.5 mL	Intramuscular	Anterolateral side of midthigh
OPV booster	16–24 months	2 drops	Oral	Oral
Measles 2nd	16–24 months	0.5 mL	Subcutaneous	Right upper arm
Rubella***	16–24 months Adolescent girls	0.5 mL	Subcutaneous	Right upper arm
JE 2nd dose	16–24 months with DPT/OPV booster	0.5 mL	Subcutaneous	Left upper arm
DPT booster 2	5–7 years	0.5 mL	Intramuscular	Upper arm
TT	10 years and 16 years	0.5 mL	Intramuscular	Upper arm
Vitamin A****				

* Give TT-2 or booster doses before 36 weeks of pregnancy. However, give these even if more than 36 weeks have passed. Give TT to a woman in labor, if she has not previously received TT.
** JE vaccine (SA 14–14-2) is given in selected endemic districts, after the campaign is over in that district.
*** Rubella vaccine will be given as part of measles 2nd dose
**** The 2nd to 9th dose of Vitamin A can be administered to children 1–5 years old during biannual rounds, in collaboration with ICDS (Integrated Child Development Services).

Table 3.2 IAP Immunization Timetable, 2014

I. IAP recommended vaccines for routine use

Age (completed weeks/ months/years)	*Vaccines*	*Comments*
Birth	BCG OPV 0 Hep – B 1	Administer these vaccines to all newborns before hospital discharge
6 weeks	DTwP 1 IPV 1 Hep – B 2 Hib 1 Rotavirus 1 PCV 1	**DTP:** • DTaP vaccine/combinations should preferably be avoided for the primary series • DTaP vaccine/combinations should be preferred in certain specific circumstances/conditions only • No need of repeating/giving additional doses of whole-cell pertussis (wP) vaccine to a child who has earlier completed the primary schedule with acellular pertussis (aP) vaccine-containing products **Polio:** • All doses of IPV may be replaced with OPV if administration of the former is unfeasible • Additional doses of OPV on all supplementary immunization activities (SIAs) • Two doses of IPV instead of 3 for primary series if started at 8 weeks, interval between the doses • No child should leave the facility without polio immunization (IPV or OPV), if indicated by the schedule **Rotavirus:** • 2 doses of RV1 and 3 doses of RV5 • RV1 should be employed in 10 and 14 week schedule, instead of 6 and 10 week schedule • 10 and 14 week schedule of RV1 is found to be far more immunogenic than existing 6 and 10 week schedule
10 weeks	DTwP 2 IPV 2 Hib 2 *Rotavirus 2 PCV 2	**Rotavirus:** • If RV1 is chosen, then the first dose should be given at 10 weeks
14 weeks	DTwP 3 IPV 3 Hib 3 *Rotavirus 3 PCV 3	**Rotavirus:** • Only 2 doses of RV1 are recommended at present • If RV1 is chosen, then the 2nd dose should be given at 14 weeks
6 months	OPV1 Hep – B3	**Hepatitis B:** The final (third or fourth) dose in the Hep B vaccine series should be administered no earlier than age 24 weeks and at least 16 weeks after the first dose

Contd…

Contd…

I. IAP recommended vaccines for routine use		
Age (completed weeks/ months/years)	*Vaccines*	*Comments*
9 months	OPV2 MMR-1	**MMR:** Measles-containing vaccine ideally should not be administered before completing 270 days or 9 months of life The 2nd dose must follow in 2nd year of life No need to give stand-alone measles vaccine
9–12 months	Typhoid Conjugate Vaccine	• Currently, two typhoid conjugate vaccines, Typbar—TCV and PedaTyph available in Indian market • PedaTyph is not yet approved; the recommendation is applicable to Typbar—TCV only • An interval of at least 4 weeks with the MMR vaccine should be maintained while administering this vaccine • Should follow a booster at 2 years of age
12 months	Hep-A1	**Hepatitis A:** • Single dose for live attenuated H2—strain Hep—A vaccine • Two doses for all killed Hep—A vaccines are recommended now
15 months	MMR2 Varicella1 PCV Booster	**MMR:** • The 2nd dose must follow in 2nd year of life • However, it can be given at anytime 4 to 8 weeks after the 1st dose **Varicella:** The risk of breakthrough varicella is lower if given 15 months onwards
16–18 months	DTwP B1/ DTaP B1 IPV B1 Hib B1	The first booster (4th dose) may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose **DTP:** • First and second boosters should preferably be of DTwP • Considering a higher reactogenicity of DTwP, DTaP can be considered for the boosters
18 months	Hep A2	**Hepatitis A:** The 2nd dose for killed vaccines; only single dose for live attenuated H2 – strain vaccine
2 years	Typhoid booster	• Either Typbar – TCV or Vi – polysaccharide (Vi – P5) can be employed as booster • Typhoid revaccination every 3 years, if Vi–polysaccharide vaccine is used • Need of revaccination following a booster of Typbar–TCV not yet determined
4–6 years	DTwP B2/ DTaP B2 OPV 3 Varicella 2 Typhoid booster	**Varicella:** The 2nd dose can be given at anytime 3 months after the 1st dose

Contd…

Contd…

I. IAP recommended vaccines for routine use		
Age (completed weeks/ months/years)	*Vaccines*	*Comments*
10–12 years	Tdap/Td HPV	**Tdap:** is preferred to Td followed by Td every 10 years **HPV:** • Only 2 doses of either of the two HPV vaccines for adolescent/ preadolescent girls aged 9 – 14 years; • For girls 15 years and older, and immune compromised individuals, 3 doses are recommended
Age (completed weeks/ months/years)	*Vaccines*	*Comments*
		• For 2 dose schedule, the minimum interval between doses should be 6 months • For 3 dose schedule, the doses can be administered at 0, 1–2 (depending on brands) and 6 months
II. IAP recommended vaccines for high-risk children (vaccines under special circumstances):*		
1. Influenza vaccine 2. Meningococcal vaccine 3. Japanese encephalitis vaccine 4. Cholera vaccine 5. Rabies vaccine 6. Yellow fever vaccine 7. Pneumococcal polysaccharide vaccine (PPSV 23)		

***High-risk category of children:**

- Congenital or acquired immunodeficiency (including HIV infection)
- Chronic cardiac, pulmonary (including asthma treated with prolonged high-dose oral corticosteroids), hematologic, renal (including nephritic syndrome), liver disease and diabetes mellitus
- Children on long-term steroids, salicylates, immunosuppressive or radiation therapy
- Diabetes mellitus, cerebrospinal fluid leak, cochlear implant, malignancies
- Children with functional / anatomic asplenia / hyposplenia
- During disease outbreaks
- Laboratory personnel and healthcare workers
- Travelers
- Children having pets in home
- Children perceived with higher threat of being bitten by dogs such as hostellers, risk of stray dog menace while going outdoor

Table 3.3 IAP Recommended Immunization Schedule for Children Aged 0–18 years (with range)

Vaccine/Age	*Birth*	*6 wk*	*10 wk*	*14 wk*	*18 wk*	*6 mo*	*9 mo*	*12 mo*	*15 mo*	*18 mo*	*19–23 mo*	*2–3 yr*	*4–6 yr*	*7–10 yr*	*11–12 yr*	*13–18 yr*
BCG	BCG															
Hep B	Hep B1	Hep B2				Hep B3										
Polio	OPV0	IPV1	IPV2	IPV3		OPV1	OPV2	IPVB1					OPV3			
DTP		DTP1	DTP2	DTP3					DTPB1				DTPB2			
Tdap															Tdap	
Hib		Hib1	Hib2	Hib3				Hib booster								
Pneumococcal		PCV1	PCV2	PCV3				PCV booster						PCV		
PPSV23												PPSV				
Rotavirus		RV1	RV2	RV3												
Measles							Measles									
MMR								MMR1					MMR2			
Varicella									VAR1				VAR2			

Contd…

Immunization in Clinical Practice

Immunization has become an important part of the clinical practice in pediatrics. The last few years have seen some exciting developments in the field of immunization. This book *Immunization in Clinical Practice* is thoroughly revised and updated with the objectives of providing the concise, reader-friendly and evidence-based scientific knowledge within a single book that incorporates both the science and art of immunization. A successful book is the sum of the contributions provided by its expert contributors. All the contributors of this book are genuine experts in the field of vaccinology. The strength of this book is knowledge, hard work and experience of its contributors. This book should serve as a reference book, especially for the practicing pediatricians, family physicians, postgraduate students and paramedics.

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