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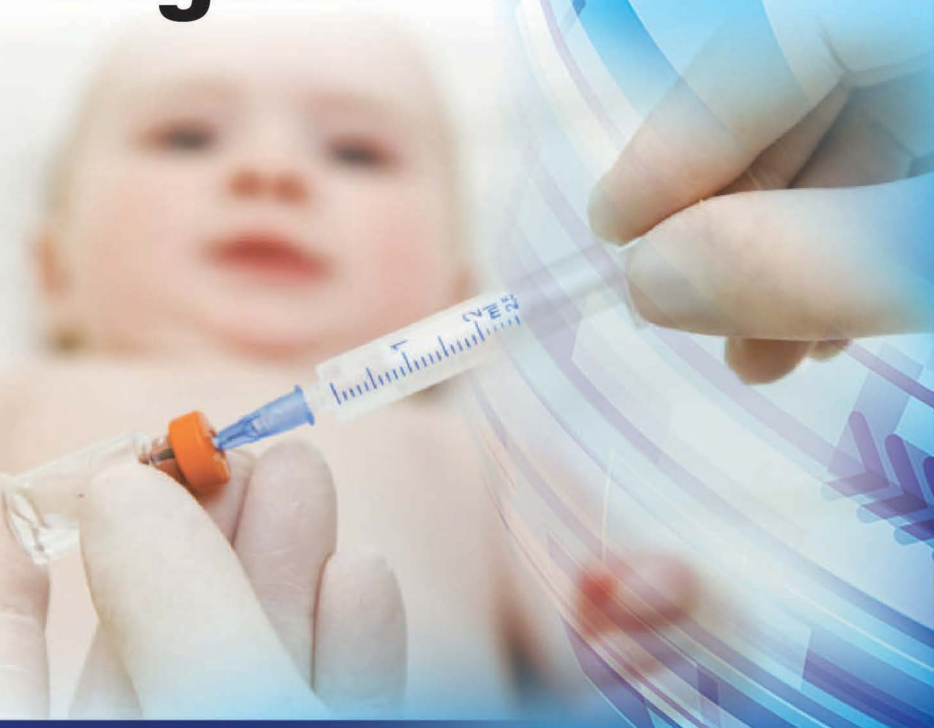
Partha's Immunization Digest



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A Parthasarathy

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CHAPTER

2

Immunization: The Way Forward

A Parthasarathy

INTRODUCTION

When Edward Jenner first administered smallpox vaccine in 1796, the process was known as variolation. Later came the use of the term *vaccination*, which was widely accepted. The term *immunization* came into vogue in due course to emphasize the importance of active immunity induced by various antigens. The Greek word *Immune* means to be protected. Whereas the protection offered by vaccines is *active*, passive protection is achieved by the administration of antisera or immunoglobulins. So, certain terminologies need to be defined carefully. Today both the terms *vaccination* and *immunization* are used interchangeably. However, the global practice is to use the term *immunization* more frequently, viz. Expanded Program on Immunization (EPI), Universal Child Immunization (UCI), Global Alliance on Vaccines and Immunization (GAVI), etc.

After the discovery of smallpox vaccine in the year 1796, it took 79 years, for Louis Pasteur to develop the killed rabies vaccine in 1885 followed by the discovery of many more monovalent childhood antigens and the discovery of the first combination vaccine DTP in 1945 and measles, mumps and rubella combined vaccine, MMR, in 1971. With advances in genetic engineering and molecular biology the future will witness the development of more new antigens and perhaps most of these new antigens will be in combination formulation.

Immunization has rightly been claimed as the greatest success story in the history of mankind in the 20th century. Eradication of smallpox in 1978 had paved the way for the elimination/eradication of similar vaccine preventable diseases in several developed countries. Many developing countries such as India too, have achieved outstanding success in eliminating vaccine preventable diseases (VPDs) such as neonatal tetanus, diphtheria, pertussis, measles, poliomyelitis, etc. Global eradication of poliomyelitis by eradicating the circulation of

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wild as well as vaccine-derived polioviruses is expected to be achieved by 2020.

Vaccines not only save lives; they help children learn and grow, they mean more days in school, they avert many debilitating risks from childhood diseases, and they reduce healthcare costs, protecting families and communities from sliding into poverty.

GAVI, NTAGI, IEAG, IPEI RECOMMENDATIONS

Following repeated representations from the Indian Academy of Pediatrics (IAP), the Government of India has constituted a National Technical Advisory Group on Immunization (NTAGI) and India Experts Advisory Group (IEAG), which considers the exiting immunization practices and India Polio Eradication Initiative (IPEI) and AFP surveillance respectively and suggest introduction of a few more vaccines into the National Immunization Schedule and Strategies to be adopted for polio eradication. It is fervently hoped that the laudable objective of *All Vaccines for the Entire World's Children* will become a reality soon.

The National Technical Advisory Group on Immunization since recommended the introduction of measles-rubella (MR) vaccine in the National Immunization Schedule in place of measles vaccine as well as DTwP Booster in place of diphtheria-tetanus (DT) at 5 years. Apart from introducing the pentavalent fully liquid DTwP-HB-Hib vaccine throughout the country, introduction of rotavirus vaccine, one dose of IPV along with 3rd dose of PENTA and the switch to bivalent OPV, viz. bOPV1 and bOPV3, replacing the conventional trivalent OPV, viz. tOPV are in place already.

The Government of India has in principle approved the introduction of pneumococcal conjugate vaccine (PCV) in the National Immunization Program (NIP), with GAVI subsidy. Introduction of the rotavirus vaccine using the indigenous monovalent 116E strain is also being contemplated. Annual campaign with a single dose of JE vaccine in JE hyperendemic areas has been successfully implemented. Introduction of MR vaccine at 16–24 months along with DTwP booster and rubella vaccine at 10 years for adolescent girls are also in the agenda. A single dose of IPV along the 3rd dose of DTwP to enhance mucosal immunity is also being considered as strategy

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towards Polio End Game. Switch from tOPV to bOPV for routine immunization and NIDs has already taken place.

DEVELOPMENT OF NEW VACCINES AND NEW TECHNIQUES FOR VACCINE ADMINISTRATION

Apart from the currently available toxin based, subunit, live organisms, inactivated organisms, polysaccharide, glycol conjugate vaccines, etc. We will be having additional or replacement vaccines, viz. anti-idiotype vaccines, re-assorted genomes, temperature sensitive mutants, recombinant viruses and bacteria, recombinant viral or bacterial vectors, genetic (DNA), plant (edible) vaccines, and transcutaneous vaccines which will revolutionize the concept of immunization.

In addition to development of new vaccines, new vaccine implementation and delivery strategies along with new developments in basic and applied immunology, including those directly related to vaccine biotechnology applied implementation, research and the bioethics of clinical trials promise to make the 21st century exciting for vaccinology. Developments such as whole genome sequencing may reveal entirely new paradigms for vaccine development. With molecular medicine's exorable advances, parallel research must progress to ensure that the scientific advances of developed countries are available in developing countries, as well.

LEARNING POINTS

Pediatric and Adolescent Immunization—yesterday, today and tomorrow:

Yesterday

Handful of vaccines, Expanded Program on Immunization (EPI), Targeted universal coverage of under 5 children and pregnant mothers, development of combination vaccine formulations, elimination and eradication of VPDs, smallpox eradication achieved.

Today

Pocketful of vaccines, EPI, UCI, Stress on Adolescent and Adult Immunization, more antigens for immunization

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during pregnancy, Global Program on Vaccines (GPV), GAVI, development of more combination vaccine formulations, newer adjuvants, newer technologies for vaccine development and administration, vaccine vial monitors to assess cold chain maintenance, elimination and eradication of VPDs, viz. Eradication of poliomyelitis, control and elimination of neonatal and maternal tetanus, diphtheria, pertussis, and measles have been achieved.

Only 30 years ago for instance, wild poliovirus was widespread across 125 countries, causing millions to endure lifelong paralysis. Last year, there were wild poliovirus infections in just two countries—Afghanistan and Pakistan—with only 33 confirmed cases reported worldwide.

Maternal and neonatal tetanus, an often-fatal disease, has been eliminated in all but 13 countries because of vaccination of women before or during pregnancy. And promising results from nations that have introduced the human papillomavirus vaccine early, suggests that cervical cancer is set to decline.

Tomorrow

Bag full of vaccines, all vaccines for all the world's children with GAVIs subsidy, more sophisticated combination vaccine formulations, needle-free vaccine patches, more antigens for universal coverage, improved cold chain equipment, elimination and eradication of more VPDs, global eradication of poliomyelitis, neonatal and maternal tetanus, measles and many more.

The new vaccines are on the horizon to protect against some of our most dangerous known pathogens. The rVSV-ZEBOV Ebola vaccine has already played a critical role in controlling the spread of the current outbreak in the Democratic Republic of the Congo, while RTS, S, the world's first ever malaria vaccine is soon going to be piloted in routine immunization programs.

BIBLIOGRAPHY

1. https://www.who.int 2019
2. John T J. National Technical Advisory Group on Immunization. Indian Pediatr. 2002;39:327-30.
3. John TJ. Towards an Ideal Vaccination Schedule in India. Indian J Pediatr. 1998;65:S8-12.

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4. National Rural Health Mission GOI document Brief overview of Universal Immunization Program in India, ASOV workshop course material, IAP, 2009.
5. Universal Immunization Program in India. Breaking New Ground. Ministry of Health and Family Welfare, Government of India; 2002;1-25.
6. Widdus R. The potential to control or eradicate infectious diseases through immunization. Vaccine. 1999;17:S6-12.
7. Yewale VN, Gupta A, Parthasarathy A. Rationale of Selection of Vaccines in National Immunization Program and IAP Immunization Timetable. In: Parthasarathy A, Nair MKC, Menon PSN, Kundu R (Eds). IAP Textbook of Pediatrics (6th edn). Jaypee Brothers Medical Publishers, New Delhi; 2016. pp. 205-17.

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Partha's
Immunization Digest

Salient Features

- An updated and revised book with detailed information on various aspects of immunization
- Practical guidelines are incorporated on Vaccine Administration and Safe Injection Practices
- Diagrams showing administering multiple vaccines at the same sitting is a visual guide for readers
- Latest National Immunization Schedule, 2019; IAP Immunization Time Table, 2018–2019; WHO Immunization Guidelines, 2019; and CDC Adult Vaccination Guidelines, 2019 with footnotes are self-explanatory and updated
- Learning points at the end of each chapter are the unique feature offering day-to-day practice-oriented learning
- Tables showing vaccine brands available in India are a ready-reckoner for the busy practitioner
- FAQs by parents and doctors have been addressed adequately
- Immunization websites and bibliography have been added for those seeking more information on vaccines and immunizations
- Basics of Vaccinology, History of Vaccines, Vaccine Development and Future Vaccine make reading this digest a pleasure.



Editor-in-Chief
A Parthasarathy



Chief Academic Editor
Alok Gupta



Academic Editor
Mohit Vohra



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