

Review Article

A review on Indian national vaccine policy

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ABSTRACT

Vaccines are one of the most successful health interventions that bring about significant reductions in infectious diseases and adverse health consequences and improve quality of life in the population. Over the years vaccines have provided highly cost effective improvements to human health by reducing avoidable human suffering, costs of care and treatment, economic consequences of work i.e. lower productivity and loss of work. More and more diseases are becoming vaccine preventable; including those for prominent killers like pneumonia and diarrhea, and the technology used is evolving rapidly. Since vaccines are administered to healthy people, especially children, it is pivotal to ascertain they are safe and cost effective. Consequently vaccine development has become time and resource intensive, with more stringent regulatory pathways to ensure safety and efficacy of vaccines. In a situation where there is abundance of new and expensive vaccines on one hand and limitations of resources on the other, it becomes imperative that use of vaccines through induction in the universal immunization program (UIP) as well as in the free market is done through a framework of decision-making that confers positive health and economic benefits to the society.

Keywords: VPDs, AEFIs, UIP

INTRODUCTION

Vaccination is a proven and one of the most cost-effective child survival interventions. All countries in the world have an immunization programme to deliver selected vaccines to the targeted beneficiaries, specially focusing on pregnant women, infants and children, who are at a high risk of diseases preventable by vaccines. There are at least 27 causative agents against which vaccines are available and many more agents are targeted for development of vaccines the number of antigens in the immunization programmes varies from country to country; however, there are a few selected antigens against diphtheria, pertussis, tetanus, poliomyelitis, measles, hepatitis B which are part of immunization programmes in most of the countries in the world.¹

UIP was given the status of a national technology mission in 1986. A specific immunization strengthening project (ISP) was designed to run from 2000-2003, which included three main components (polio eradication, strengthening routine immunization (RI), and strategic framework for development).

The overarching goal of the UIP is to reduce morbidity and mortality due to vaccine preventable diseases (VPD). While surveillance information for specific VPDs is limited, the steady fall of IMR from 123 to 50 deaths per 1000 live-births (SRS 2011) does in part reflect the impact of the UIP. Besides, in the past 15 years, a decline in the reported number of cases of the main VPDs (diphtheria, tetanus, pertussis and measles) has been observed. The same data though does show an increase in the number of reported measles, diphtheria and pertussis

cases in recent years with measles continuing to be responsible for 6% of childhood mortality or 80,000 deaths annually. Since its launch in 1995, the polio pulse campaign aimed at eradicating polio from India, has begun to show results. Government efforts have brought India closer to the goal of polio eradication than ever before in history with only 42 confirmed cases in 2010 and only one in 2011.²

As a part of the broader national health policy, a national vaccine policy is needed, based on the principles of public health and comprehensive primary health care. This is to enable rational and evidence-based decisions for the development, entry, production, stable supply, pricing, promotion and use of appropriate vaccines on scientific grounds. Additionally, this is also needed to protect the national vaccine programmes and national health security, as well as to leverage indigenous capabilities to cater to domestic and overseas markets.

Objectives of the national vaccine policy:

1. To contribute to prevention of mortality and morbidity due to communicable diseases.
2. To ensure consistent delivery and administration of vaccines to everyone in need.
3. To achieve national self-reliance in vaccine R&D.
4. To achieve pre-eminence in the capabilities of the indigenous public sector for self-reliance.
5. To develop and use the interdisciplinary knowledge base.
6. To promote ethical conduct in the development, trials, adoption and administration of vaccines.
7. To develop a system for monitoring and compensating AEFI.
8. To enable India to play a leading role in the supply of affordable vaccines.
9. To synergize all relevant policies for effective implementation of the national vaccine policy.

The national policy of immunization under universal immunisation programme is phased in manner as seen in following Table 1.³

UIP in India and its core antigens have made a significant impact on the burden of diseases in the country and directly contributed to reducing child mortality. There is limited production capacity of these vaccines in public sector units and the involvement of private sector manufacturers is required to ensure that supply of UIP vaccine is not threatened.

For new and underutilized vaccines, there is need for the institutionalizing and strengthening of decision making process in-built country mechanism for sustainable production of newer vaccines within country.

India has a leading vaccine industry; however, there is need for investing more on the research for the vaccines for the priority diseases in the country.

For potentially new vaccines and vaccine security issues, the implementation of immunization program should be put in the perspective of broader goals of National Health Policy. The sufficient political will & support, and financing mechanisms should also be ensured for this purpose.⁴

Situation analysis

India's vaccine industry ranks third in terms of volume globally in the world. The impact of vaccination suggest that IMR in India had fallen steadily to reach 40 deaths per 1000 live-birth as per sample registration system in 2013, while as per sample registration system 2012 it was 52 per 1000 live births. National vaccination coverage is believed to be around 72%. However, there are major differences in coverage among the states, ranging from below 30% to above 90% in some states. The private health sector provides an estimated 15-20% of immunization services.⁵

14 states with measles coverage <80% – (Arunachal Pradesh, Assam, Bihar, Chattisgarh, Gujarat, Haryana, Jharkhand, M.P, Manipur, Meghalaya, Nagaland, Rajasthan, Tripura and U.P). In the remaining 21 states with better performing routine immunization systems (i.e., ≥80% routine measles coverage).⁶

It has been three years without any fresh cases of polio; India has officially eliminated the much dreaded disease effective January 2014.⁷

The elimination of maternal and neonatal tetanus comes a year after India eradicated polio. Maternal and neonatal tetanus is now reduced to less than one case per 1000 live births in all 675 districts of the country.⁸

Haemophilus influenzae type b (Hib) vaccines, Pneumococcal conjugate vaccines, Rotavirus vaccines, HPV vaccines, which have estimated reducing child mortality in India.⁹

Barriers to strengthen immunization programme

There are well recognized challenges in the implementation of immunization program in the country as follows:

- Weak VPD surveillance system.
- Lack of data on disease burden in India.
- Lack of diagnostic tools and specialized training for certain VPD.
- Lack of baseline surveillance data.
- Limited economic evaluations.
- Lack of a financial sustainability plan for the introduction of new vaccines.¹⁰

Vaccine research and development

The research and development of vaccines for locally prevalent diseases like pneumonia, diarrhoea, JE, dengue, cholera, typhoid and diseases like leishmaniasis etc. in India should be given a priority.¹¹

India has a number of institutions, where vaccine related projects are executed i.e. Indian Council of Medical Research (ICMR), Department of Science and

Technology (DST), Council for Scientific and Industrial Research (CSIR), small and medium vaccine industries, medical and engineering schools, in addition to the Department of Biotechnology (DBT) supported autonomous institutions. A number of linkages need to be discovered between academia, industry and international institutions such as NIH/NIAID, Gates Foundation, GAVI Alliance, PATH, WHO and the International Centre for Genetic Engineering and Biotechnology (ICGEB).¹⁰

Table 1: National immunization schedule for infants, children and pregnant women.

Vaccine	When to give	Dose	Route	Site
For pregnant women				
TT-1	Early in pregnancy	0.5ml	Intramuscular	Upper arm
TT-2	4 weeks after TT-1*	0.5ml	Intramuscular	Upper arm
TT- booster	If received 2 TT doses in a pregnancy within last 3 years*	0.5ml	Intramuscular	Upper arm
For infants				
BCG	At birth or as early as possible till one year of age	0.1ml (0.05ml till 1 moth age)	Intra dermal	Left upper arm
Hepatitis	At birth or as early as possible within 24 hours	0.5ml	Intra muscular	Antero lateral side of mid-thigh
OPV-0	At birth or as early as possible within 15 days	2 drops	Oral	Oral
OPV-1, 2 & 3	At 6weeks,10weeks &14weeks	2 drops	Oral	Oral
DPT 1, 2 & 3	At 6weeks,10weeks &14weeks	0.5ml	Intramuscular	Antero lateral side of mid-thigh
Hep B 1, 2 & 3	At 6weeks,10weeks&14weeks	0.5ml	Intramuscular	Antero lateral side of mid-thigh
Measles	9 completed months -12 months	0.5ml	Subcutaneous	Right upper arm
Vitamin – A (1 st dose)	At 9 months with measles	1ml (1 lakh IU)	Oral	Oral
For children				
DPT booster	16-24 month	0.5 ml	Intra muscular	Antero-lateral side of mid thigh
Measles 2 nd dose	16-24 month	0.5ml	Subcutaneous	Right upper arm
OPV booster	16-24month	2 drops	Oral	Oral
Japanese encephalitis **	16-24 month	0.5ml	Subcutaneous	Left upper arm
Vitamin – A ***				
(2 nd to 9 th dose)	16 months then one dose every 6 month upto age of 5 years	2 ml (2 lakh IU)	Oral	Oral
DPT booster	5-6 years	0.5 ml	Intra muscular	Upper arm
TT	10 years & 16 years	0.5 ml	Intra muscular	Upper arm

*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 labour, if she has not previously received TT; **JE vaccine. In select endemic districts after the campaign; ***The 2nd to 9th doses of Vitamin A can be administered to children 1-5 years old during biannual rounds. In collaboration with ICDS.

Creation of bio-repositories

Bio repository is a confidential list of people who are willing to participate in a vaccine study, have had a virus or who have lived in a dengue virus risk area and are willing to participate in one of our studies.¹²

Banking of biological samples both sera and organisms that are collected during diseases surveillance, epidemics or clinical trials can be a tremendous source of materials

for retrospective use in case of re-emergence of a disease. Administration, management, custodianship, and security of bio banks can be major issues.

The existing guidelines that govern the functioning of a national bio repository in India and the best practices followed in other countries should be examined and an India specific standard operating procedure and

guidelines needs to be drafted with appropriate linkages with different programs.

The concept of public private partnership (PPP) has aided in bridging the gaps between academia, industry, and funding agencies successfully. The PPPs have also evolved innovative methods for intellectual property and portfolio management, and has unique structures and methods for governance.

An indigenous new generation oral cholera vaccine has also been brought to the market with the partners being International vaccine institute, Korea, National institute of cholera and other enteric diseases (NICED), Kolkata, and Shantha Bio technics Ltd, Hyderabad.¹⁰

AIDS vaccine trials have accelerated significantly in India in recent years. Activities include an adeno-associated virus vector Phase I trial, MVA vector vaccine trials and a recent DNA/MVA Phase I prime-boost trial initiated in 2009.¹³ The International AIDS Vaccine Initiative (IAVI) is supporting Indian AIDS vaccine clinical trials and applied research on neutralizing antibody immunogens.¹⁴

Vaccine production and supply

India is one of the major suppliers to UN agencies of pre-qualified vaccines approximately 43% of global vaccine supply is provided by Indian manufacturers, primarily from the private sector. All immunization program (NIP) vaccines supplied are from WHO non pre-qualified manufacturers except of measles vaccine.²

National technical advisory group on immunization (NTAGI)

NTAGI is a group of experts from vaccination and immunization related fields in India. New vaccines to be introduced as per national technical advisory group on immunization (NTAGI) recommendation.¹⁵

Injectable polio vaccine (IPV)

NTAGI recommended injectable polio vaccine (IPV) introduction as an additional dose along with 3rd dose of DPT in the entire country in the first quarter of 2016.

Rota virus vaccine

NTAGI recommended the introduction of rotavirus vaccine in universal immunization programme in a phased manner.

Rubella vaccine

It is to be introduced as MR vaccine replacing the measles containing vaccine first dose (MCV1) at 9 months and second dose (MCV2) at 16-24 months. On September 23, 2013 NTAGI endorsed scale-up of

pentavalent vaccine in the remaining 27 states in a phased manner with simultaneous strengthening of the AEFI and sentinel surveillance systems. NTAGI advises the national government regarding the technical issues related to the vaccination and immunization.¹⁶

Operational efficiency of UIP

Operational efficiency of UIP consists of improving vaccine coverage AEFI surveillance system, VPD surveillance, Vaccine forecasting, procurement and management.

Improving vaccine coverage

In India, even though Indian vaccine manufacturers supply over 43 percent of the global vaccine requirements, the average of national coverage of the essential vaccines under the UIP in India is below 50 percent. The UIP in India targets 2.7 crore infants with a domestic market of 100 million doses. The coverage of UIP vaccines in this country is >70% only in 11 states, 50-70% in 13 and below 50 % in the rest of the 8 states. 179 Japanese encephalitis (JE) endemic districts across 20 states have been identified. JE vaccination campaign has been completed in 154 districts covering nearly 108 million children; remaining districts will be covered till March 2015.¹⁷

Pentavalent vaccine has been introduced in 8 States/UTs i.e. Tamil Nadu, Kerala, Haryana, J&K, Gujarat, Karnataka, Goa and Puducherry. Pentavalent vaccine expansion is planned in 12 States/UTs i.e. Andhra Pradesh, Telangana, Assam, Bihar, Chhattisgarh, Jharkhand, Madhya Pradesh, Punjab, Rajasthan, West Bengal, Delhi, Uttarakhand by December 2014.

Adverse events following immunization surveillance system

The national operational guidelines on AEFI surveillance has been updated in 2010.

The Central Drug Laboratory used for testing for vaccine samples in AEFI are,

- Central Drugs Testing Laboratory, Mumbai, Maharashtra, India
- Central Drugs Laboratory, Kolkata, West Bengal, India
- Central Drugs Testing Laboratory, Chennai, Tamil Nadu, India
- Central Drugs Testing Laboratory, Hyderabad, Andhra Pradesh, India
- Central Drugs Laboratory, Central Research Institute, Kasauli, H.P., India
- Regional Drugs Testing Laboratory, Guwahati, Assam, India
- Regional Drugs Testing Laboratory, Chandigarh, India

- National Institute of Biological, Noida (U.P.), India

VPD surveillance

Amongst different surveillance models under vertical national health programs targeted for disease control, elimination or eradication in India, integrated disease surveillance project (IDSP) is one of those surveillance systems. IDSP is a case-based surveillance system for detection of early warning signals of outbreaks. The national polio surveillance project (NPSP) has done extremely well in acute flaccid paralysis (AFP) surveillance in India. The efforts for inclusion of Hib and pneumococcal pneumonia and meningitis surveillance under IDSP has already being done.

Vaccine forecasting, procurement and management

All UIP vaccines are purchased at the central level for distribution to the states under the broad overarching General Financing Rules (GFR). The vaccines are purchased using annual rate contracts (as per GFR) against which supply orders are issued. Parallel contracts are awarded for most vaccines. The current dependence on a limited number of domestic vaccine producers leaves the UIP vulnerable to price increases and supply shortages.^{10,18}

Development of RI logo

The new logo of the baby holding the syringe, indicating routine immunization (RI) as his right, has been developed in purple colour. This will give RI a distinct identity. Deliberate efforts have been made to stay away from the Polio brand colours of yellow and pink.¹⁹



Figure 1: RI logo

Vaccine wastage

An assessment of vaccine wastage in India, conducted in 2009 revealed that wastage rates depended on formulation, presentation and was inversely proportional to session size. Both cold chain requirement and vaccine wastage is expected to increase several fold with the introduction of newer vaccines compared to the UIP vaccines.²⁰

Following table shows wastage of six vaccines commonly used in the programme, which are administered according to the national immunization schedule.

Table 2: Wastage of six vaccines commonly used in the programme, which are administered according to the national immunization schedule.

Vaccine	% Wastage
DPT (Diphtheria, pertussis, tetanus), DT (Diphtheria, tetanus), TT (tetanus) and OPV (Oral polio vaccine)	25%
BCG (for Tuberculosis)	50%
Measles	25%

Use of phase change materials (PCMs) can help reduce vaccine wastage during transportation. The present size of immunization division is extremely small, given the size of the country and number of beneficiaries to be serviced. Capacity building needs to be supported on a sustainable basis and should be adequately stressed in the national budget.⁴

Implementation

On August 31, 2009 the Ministry of health and family welfare convened a meeting chaired by the additional secretary & director of national rural health mission, specifically to address various elements in UIP design and implementation (captured in the phrase, 're-engineering'). Follow up action is still awaited.¹⁰

Mission Indradhanush

The result is the 'Mission Indradhanush' launched on 25th December, 2014 with an aim to cover all those children who are partially vaccinated or unvaccinated. 'Mission Indradhanush' is a nationwide initiative with a special focus on 201 high focus districts. These districts account for nearly 50% of the total partially vaccinated or unvaccinated children in the country. Mission Indradhanush will provide protection against seven life-threatening diseases (diphtheria, whooping cough, tetanus, polio, tuberculosis, measles and hepatitis B). In addition, vaccination against Japanese encephalitis and *Haemophilus influenzae* type B will be provided in selected districts of the country. Vaccination against tetanus will be provided to the pregnant women.

Between 2009-2013 immunisation coverage has increased from 61% to 65%, indicating only 1% increase in coverage every year. To accelerate the process of immunization by covering 5% and more children every year, the mission mode has been adopted to achieve target of full coverage by 2020. High-focus 201 districts will be taken up for implementation in the first phase. Of these, 82 districts are in just four states of UP, Bihar, Madhya Pradesh and Rajasthan and nearly 25% of the unvaccinated or partially vaccinated children of India are in these 82 districts of four states. Moreover, 297 will be targeted for the second phase. The Mission focuses on interventions to rapidly increase full immunization

coverage of children by approximately 5% annually and to expand full immunization coverage from 65% in 2014 to at least 90% children in the next five years. Four special vaccination campaigns will be conducted between March and June 2015 and this will cover all children less than two years of age and pregnant women for tetanus toxoid vaccine. This immunization campaign will be conducted for a period of 7-10 days every month for four consecutive months.

Micro plans developed to make the mission mode successful will draw on the lessons learned from the polio eradication towards systems strengthening, vaccine cold chain management, regular surveillance and monitoring of the plans to reach each and every left out and uncovered child. The government has sought technical support from various external agencies like WHO, UNICEF and rotary to achieve the goals of this programme.¹

CONCLUSION

India enjoyed the advantages of early initial successes in vaccine R&D and indigenous production in the public sector, but the country is increasingly unable to cope with the growing gap in the demand and supply of UIP vaccines. The availability of UIP vaccines from the private sector is also on the decline in India and abroad, in favor of more expensive new vaccines and combination vaccines, whose public health need has not been unequivocally established in India with sound epidemiological and cost-benefit data. Therefore, India (and indeed, every country) must evolve its own national strategies to meet its vaccination needs within its budgetary constraints. To do so will require following are key actions. The first and foremost element is the decisive intervention of the Indian government to meet the shortfall in the UIP vaccines. Secondly, India needs to strengthen epidemiology and revive the collapsing disease surveillance system. Thirdly, a strong emphasis on in-house R&D is needed. Lastly, the Indian government should actively encourage independent policy research, cost-benefit studies, and wider national consultations.

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