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REVIEW ARTICLE

# National Immunization Programme – Mission Indradhanush Programme: Newer Approaches and Interventions

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**Abstract**
Vaccines are globally accepted as instrumental in drastically bringing down vaccine preventable diseases (VPDs) related mortality and morbidity. Despite global relentless efforts, about 19.3 million children still go missing for full immunization and are at risk for VPDs. Government of India has tried to rejuvenate its four decades old Universal Immunization Programme (UIP) by recently launching Mission Indradhanush in 2014, followed by Intensified Mission Indradhanush in 2017 to boost up immunization coverage. UIP have also brought in newer vaccines, changed dose schedules, open vial policy and a robust surveillance system. Even then, country's average immunization coverage is much below par. Thus, there is a pressing need for transforming immunization program from simple vaccine delivery platform to a comprehensive disease control programme. Country should introduce newer vaccines through evidence-based policies and increase access to immunization services through system strengthening.

**Keywords** Immunization · Vaccines · Mission Indradhanush · Universal immunization programme

## Introduction

Vaccination under Routine Immunization (RI) is one of the most cost-effective health investment any country could make. Global relentless efforts to reach vulnerable in hard-to-reach pocket areas have saved countless lives over the years. Such an intervention not only protects individuals against disabling diseases but also marks opportunity for leading a healthier and more productive life [1].

However, even today, vaccine-preventable diseases (VPDs) remain most common cause of childhood mortality, estimating around 1.5 million deaths each year [2]. According to Centre for Disease Control and Prevention (CDC) 2010 report, about 19.3 million children either are partially vaccinated or unvaccinated and are at risk for VPDs-related morbidity and mortality; half of which still harbors in India, Nigeria, and Congo [3]. Presently, India is lagging behind in immunization-related services. National Family Health Survey-4 (NFHS-4) cites that national full immunization coverage against six vaccines [Bacillus Calmette-Guérin (BCG), measles, and three doses each of polio and Diptheria, Pertussis, Tetanus (DPT)] among children in 12–23 mo of age has reached only up to 62% that widely ranges between 35.7% in Nagaland and 91.1% in Puducherry (Table 1) [4]. Around 15 states/ Union Territories (UTs) are still performing below national average. No states/ UTs except Puducherry have achieved target of ≥90% immunization coverage. The country reports a dropout rate of 10.8% and 13.5% from BCG to measles and DPT-3 respectively [4], much higher among migrants with poor service utilization [5].

India being a signatory to Sustainable Development Goals (SDGs) is committed to warrant universal immunization coverage by 2030. India's immunization programme underwent many recent changes to address known determinants for country's poor immunization coverage. Government of India (GoI) launched "Mission Indradhanush" in 2014 and later "Intensified Mission Indradhanush" in 2017 that targets high-risk areas with traditional low immunization coverage to achieve 90% immunization coverage by 2018 [6, 7]. However, to reach a cohort of more than 89 lakhs missing children, dwelling in hard-to-reach and underserved areas, is still a huge programmatic challenge [7].

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**Table 1** State/Union territory-wise immunization coverage data for children aged 12–23 mo based on National Family Health Survey (NFHS-4) [4]

| S. No. | | Fully Immunized* (%) | BCG¥ (%) | DPT± 3 (%) | Measles (%) | Public health facility (%) |
|---|---|---|---|---|---|---|
| 1. | Nagaland | 35.7 | 68.4 | 52.0 | 50.4 | 91.7 |
| 2. | Arunachal Pradesh | 38.2 | 70.9 | 53.7 | 54.6 | 93.9 |
| 3. | Dadra & Nagar Haveli | 43.2 | 88.9 | 73.3 | 81.7 | 90.2 |
| 4. | Assam | 47.1 | 82.3 | 66.5 | 71.4 | 93.3 |
| 5. | Gujarat | 50.4 | 87.9 | 72.7 | 75.0 | 87.1 |
| 6. | Mizoram | 50.5 | 75.3 | 61.7 | 61.1 | 92.2 |
| 7. | Uttar Pradesh | 51.1 | 87.6 | 66.5 | 70.8 | 84.5 |
| 8. | Madhya Pradesh | 53.6 | 91.6 | 73.4 | 79.6 | 95.7 |
| 9. | Tripura | 54.5 | 82.4 | 71.1 | 69.7 | 97.4 |
| 10. | Rajasthan | 54.8 | 88.8 | 71.6 | 78.1 | 94.4 |
| 11. | Maharashtra | 56.3 | 90.0 | 74.9 | 82.8 | 86.2 |
| 12. | Uttarakhand | 57.7 | 92.9 | 80.0 | 80.6 | 91.0 |
| 13. | Meghalaya | 61.5 | 86.0 | 74.0 | 71.9 | 92.4 |
| 14. | Bihar | 61.7 | 91.7 | 80.2 | 79.4 | 95.5 |
| 15. | Jharkhand | 61.9 | 95.8 | 82.4 | 82.6 | 95.3 |
| 16. | India | 62.0 | 91.9 | 78.4 | 81.1 | 90.7 |
| 17. | Haryana | 62.2 | 92.8 | 76.5 | 79.0 | 94.8 |
| 18. | Karnataka | 62.6 | 92.5 | 77.9 | 82.4 | 88.2 |
| 19. | Andhra Pradesh | 65.3 | 97.3 | 89.0 | 89.4 | 91.6 |
| 20. | Manipur | 65.8 | 91.2 | 77.8 | 74.2 | 92.9 |
| 21. | Daman & Diu | 66.3 | 84.3 | 74.0 | 79.1 | 72.2 |
| 22. | NCT Delhi | 66.4 | 94.7 | 83.7 | 90.5 | 92.3 |
| 23. | Telangana | 68.1 | 97.4 | 87.9 | 90.6 | 83.7 |
| 24. | Himachal Pradesh | 69.5 | 94.8 | 85.0 | 87.5 | 97.9 |
| 25. | Tamil Nadu | 69.7 | 94.9 | 84.5 | 85.1 | 86.1 |
| 26. | Andaman & Nicobar | 73.2 | 87.4 | 83.5 | 76.4 | 94.4 |
| 27. | Jammu & Kashmir | 75.1 | 95.6 | 88.1 | 86.2 | 97.5 |
| 28. | Chhattisgarh | 76.4 | 98.4 | 91.4 | 93.9 | 96.4 |
| 29. | Odisha | 78.6 | 94.1 | 89.2 | 87.9 | 98.3 |
| 30. | Chandigarh | 79.5 | 95.9 | 95.9 | 95.9 | 93.1 |
| 31. | Kerala | 82.1 | 98.1 | 90.4 | 89.4 | 77.6 |
| 32. | Sikkim | 83.0 | 98.9 | 93.0 | 93.3 | 94.1 |
| 33. | West Bengal | 84.4 | 97.5 | 92.7 | 92.8 | 96.6 |
| 34. | Lakswadweep | 86.9 | 100.0 | 94.2 | 92.5 | 100.0 |
| 35. | Goa | 88.4 | 100.0 | 94.2 | 96.5 | 77.2 |
| 36. | Punjab | 89.1 | 98.2 | 94.5 | 93.1 | 89.0 |
| 37. | Puducherry | 91.3 | 99.9 | 96.0 | 95.4 | 89.7 |

* Immunized with BCG, Measles, and 3 doses each of Polio and Diptheria, Pertussis, Tetanus Toxoid; ± *DPT* Diptheria, Pertussis, Tetanus Toxoid; ¥ *BCG* Bacillus Calmette-Guérin

In 2018, world celebrates 44 y of launch of Expanded Programme on Immunization (EPI), this article analyzes immunization programme of India, to guide country's policy makers to re-evaluate, deliberate and take appropriate steps to ensure extended benefits of vaccines to all eligible children.

## Evolution of India's Immunization Programme – A Brief Overview

Year 2018 marked 40 y since GoI formally launched a nationwide Expanded Programme on Immunization (EPI) in 1978, that later expanded to Universal Immunization Programme (UIP) in 1985 (Fig. 1). Since then, programme dynamics has evolved over the years. India, along with WHO-South East Asia Region (SEAR), was declared polio-free; the country achieved Maternal and neonatal tetanus elimination (MNTE). Both these achievements were direct result of UIP. To address changing public health needs of country, UIP underwent certain recent changes. This includes addition of newer vaccines, incorporation of 2-dose schedule for Measles-rubella (MR) and Japanese encephalitis (JE), open vial policy implementation, VPDs surveillance, strengthened reporting of Adverse event following immunization (AEFI), Mission Indradhanush *etc*. GoI continues to encourage and support all endeavors to further strengthen and improve capacity of health workers, helping them improve their work quality. Presently, total 9 million immunization sessions are occurring yearly in India catering to an annual birth cohort of 27 million children and supported by nearly 1.5 lakh Auxiliary Nurse Midwives (ANMs) and 27,000 cold chain points. With the introduction of Pneumococcal Conjugate Vaccine (PCV) under UIP in 2017, India's UIP is now providing protection against twelve VPDs which includes tuberculosis, polio, diphtheria, pertussis, tetanus, hepatitis B (Hep B), *Haemophilus influenza* type B (Hib), rotavirus, Japanese encephalitis (JE) (in endemic districts), measles, rubella, and pneumococcal pneumonia under the common flagship of National Health Mission. Medical officers and peripheral health workers including ANMs, Accredited Social Health Activist (ASHA), Anganwadi workers continue to be its backbone.

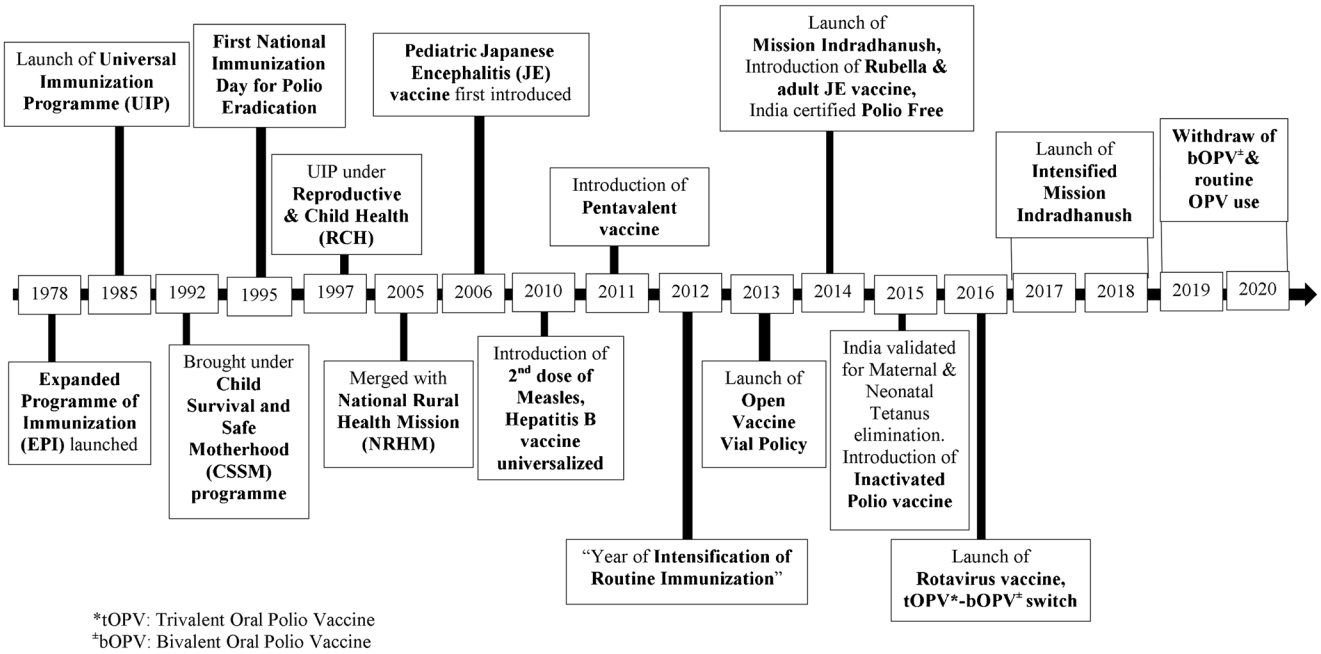


**Fig. 1** Flowchart of milestones achieved in Immunization Programme of India (1978–2020)

## Launch of "Mission Indradhanush" in 2014

Despite UIP being operational for more than 30 y, country could fully immunize only 65% children in their first year of life as per the data of Rapid Survey on Children (RSOC), (2013–14). This translates into a cohort of 89 lakhs children, dwelling in hard-to-reach and underserved areas, that goes missing and is at risk of VPDs. Moreover, there was a mere 1% annual increment in immunization coverage rate between 2009 and 2013. Therefore, Mission Indradhanush was envisaged in 2015 to achieve 90% of full immunization coverage by 2020. Focusing on 216 high focus districts across 27 states/UTs, it targets 400,000 high-risk areas with traditionally low coverage. Implemented in phased manner, it covered about 528 districts [7, 8]. Its initial two phases led to an annual increase in full immunization coverage by 6.7% compared to 1% in past [9].

## Vaccination Coverage as per NFHS

NFHS-based trend comparison showed that prior to NRHM, full immunization coverage in India improved at a sluggish pace *i.e.,* from 35.4% in 1992–93 to 42% in 1998–99, and 44% in 2005–06. Most recent NFHS-4 (2015–16) has revealed increase in immunization coverage to 62%. Although post-NRHM and launch of Mission Indradhanush, pace of improvement in immunization coverage has accelerated but it leaves much to desire especially when there is dramatic achievement in institutional birth that improved from similar low levels (39%) in 2005–06 to 79% in 2015–16. This raises a fundamental policy question: why does immunization coverage persists to fall behind despite decades of publicly financed UIP? Given the pace of progress as revealed in NFHS-4, policymakers are concerned about country's performance on immunization front [4].

The other major concern is the existing rural-urban differences and socioeconomic hierarchies. Most progress has reportedly come from rural areas (from 39% to 61%) with urban areas strikingly witnessing low improvements (from 58% to 64%). Improvements in coverage are better among poorest households (those belonging to lowest wealth quintiles) compared to those from better-off sections (higher wealth quintiles) (Fig. 2). In fact, there is seen a worrisome stagnation in coverage (at 70%) among those belonging to highest wealth quintile [4].

## Introduction of "Intensified Mission Indradhanush" in 2017

A worrisome record in urban areas and even among better-off sections of society called for re-examining this broad policy direction. The increase under Mission Indradhanush was not sufficient to achieve its target by 2020. Moreover, certain districts/urban cities showed slow progress despite repeated phases. MoHFW drew an aggressive action plan to prepone the target by 2018. Under this plan, states conducted "Intensified Mission Indradhanush" drives to cover all left outs in 118 priority districts including 52 Northeastern districts, and 17 urban cities with identified low coverage. It is carried out for seven working days from seventh day of every

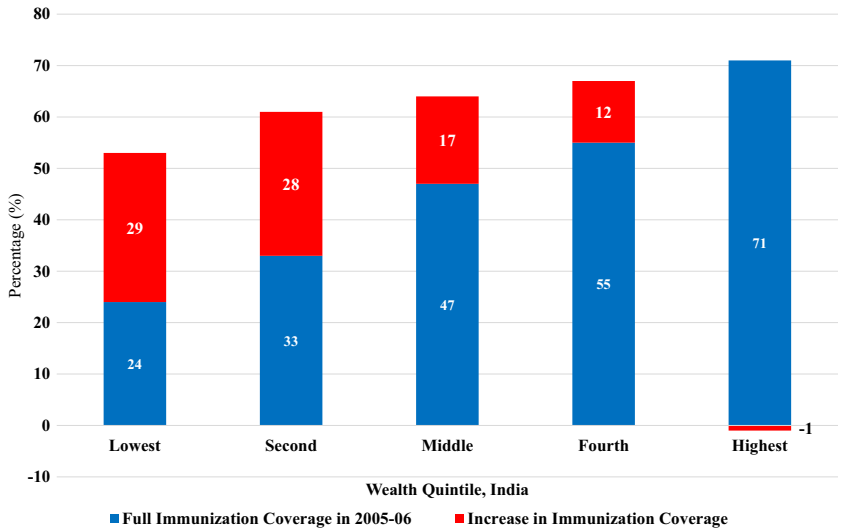


**Fig. 2** Full immunization coverage (%) in 2005–06 and increase in full immunization in 2015–16 by Household Wealth Quintile Index, India [4]

month, starting from 7 October 2017 for four consecutive months – excluding Sundays, holidays and RI days. It largely focused on convergence with other ministries/departments especially Women and Child Development, Panchayati Raj, Urban Development, Youth Affairs *etc.* including ground level workers, which was crucial for its successful implementation [7].

## Few Debatable Issues in Immunization

Despite country's relentless efforts to address various barriers of immunization coverage [6–9], only few states are able to maintain immunization coverage between 85 and 90% [4]. Given enormous challenge, it is important to explore determinants of immunization coverage, other than socio-demographic (literacy, gender, socioeconomic status) [10], demand (lack of awareness, cultural beliefs, distance to health facility), and supply side factors (poor service quality, inadequate staffing, irregular vaccines supply) [10, 11] on which NRHM had limited impact.

Moreover, when UIP is known to benefit community by reducing VPD incidence, related mortality and morbidity, it is pertinent to identify why do we need to resort for episodic immunization campaigns for improving coverage? The answer partly lies in the fact that real immunization benefit quantified by true reduction in disease incidence is not monitored in real time. UIP does not know what it has actually achieved quantitatively by way of disease burden reduction, the true outcome intended of UIP. Consequently, neither the taxpayer community nor the science, media correspondents or parents of children get validated information on actual achievements of UIP. Hence, immunization remains as a ritual for the provider and for the people [12].

Notably Bill and Melinda Gates Foundation (BMGF) that has been contributing immensely for vaccination programmes through its ongoing project – Global Alliance for Vaccine and Immunization (GAVI) is not registered under Foreign Contribution Regulation Act (FCRA), thus has been recently placed on 'watch list'. In the beginning, vaccination program is pushed by BMGF with initial financial support. Once introduced in national programme, this support is withdrawn and entire burden comes on government. Nearly 25 million infants are given Pentavalent vaccination every year at a cost of Rs 525 per child compared to Rs 15 per child on DTP vaccination alone earlier [13].

UIP faces more problems other than low coverage alone. In the last five years, GoI launched some newer vaccines. On 26 March 2016, India became first among all Asian countries to launch rotavirus vaccine in UIP as per National Technical Advisory Group on Immunisation (NTAGI) recommendations [14]. However, it faced controversy soon after its launch. WHO recommended universal rotavirus vaccination for all regions much before regional evidence on vaccine effectiveness was collected [15]. Study published in Lancet (2010) showed no significant death reduction in vaccine group (four deaths) compared to placebo recipients (three deaths) [16]. An Indian study documented more than half (58%) of rotavirus positive cases co-infected with other pathogens; attributing all deaths to rotavirus whenever virus is isolated as overestimates of mortality [17]. It is well known that bacterial diarrhea, unlike rotavirus, is more often associated with sepsis and systemic complications, and have higher mortality [18]. The deaths due to rotavirus are amenable to prevention by simple measures like correcting dehydration [17]. Launch of rotavirus vaccine in UIP warrants a relook into the recommendation. Till November 2016, approximately 28 lakh doses of rotavirus have been administered [14].

India's decision to integrate PCV into UIP in 2017 was in response to high pneumococcal disease burden in country [19]. GoI planned to roll out PCV in phased manner and eventually extending coverage across the entire country, in coming

years [20]. However, its progress remains slow partly due to its high cost [21, 22]. In addition, uncertainty regarding its cost-effectiveness revolves around potential differences in its local distribution of prevalent serotypes, host population characteristics, health system, and vaccination programme [23]. There still exists paucity of information on asymptomatic carriage, distribution of invasive pneumococcal disease (IPD) causing serotypes in India [24] and their potential changes post-vaccine introduction. This warrants collection of data on pneumococcal carriage, disease, prevalent serotypes and their virulence and continual surveillance post PCV introduction for better understanding of pneumococcal dynamics.

In 2011, GoI introduced Pentavalent vaccine into UIP containing Diphtheria, Pertussis, Tetanus (DPT), Hepatitis B and Hib antigens [25]. In addition, birth dose of Hep B is also given for all newborns delivered within 24 h of delivery [26]. However, this combination vaccine is not licensed for use in any other developed countries [27]. Moreover, prior to introduction in India, this vaccine was used in Bhutan [28], Sri Lanka [29] and Pakistan [30]. Due to number of unexplained deaths (that were later explained as 'unrelated to immunization following revision of AEFI classification [29]) soon after pentavalent immunization; all three countries suspended the immunization drive [29, 30]. Despite huge protests, NTAGI mandated prior introduction of pentavalent vaccine in immunization programmes of two states (Tamil Nadu and Kerala). Within 20 h of launch on Dec 14, 2011, first death was reported followed by series of reports on several cases of serious AEFIs including infant deaths; total 34 deaths (at least) were reported [31]. Within no time, pentavalent vaccine was formally launched in the country. Moreover, interestingly even after immunization with Hib vaccine, a child may still acquire pneumonia, meningitis, or flu caused by other bacteria and viruses [32]. In India, there is no clear epidemiological evidence on burden of Hib infection in children and so there is no real evidence to prove that this combination is unavoidable in UIP [27, 33].

Epidemiological evidence on cancer cervix and human papilloma virus (HPV) are still inconsistent in India. Long natural history, high vaccine cost, low acceptance, and unknown duration of protection altogether influence its probability of introduction under UIP [33]. Though India has received $500 million aid from GAVI to roll out vaccines including HPV, it was not included in GoI current 2013–2017 plan, impending NTAGI recommendation and political approval. Presently, HPV is amidst controversy in India since 2009 [34]. When a clinical trial conducted by American non-profit PATH (Program for Appropriate Technology in Health), an international NGO, in partnership with Andhra Pradesh and Gujarat governments, Indian Council of Medical Research (ICMR) and Drug Controller General of India (DCGI), was suspended following death of seven pre-adolescent girls post HPV vaccination with Gardasil, (quadrivalent vaccine), and Cervarix (bivalent vaccine) [35]. Since then, its inclusion under UIP awaits Supreme Court decision on case.

Despite community-wide immunization, there are still prevailing diphtheria, measles and JE outbreaks along with continuing high childhood TB incidence in many states. Low immunization coverage could not explain this problem. As children who had been vaccinated as per schedule are reportedly acquiring these diseases later in life, one needs to know if vaccine quality is faulty or if schedule is not appropriate for best possible vaccine effectiveness. How many children have been protected from hepatitis B infection, chronic carrier state and clinical hepatitis B since launched under UIP? How many Hib meningitis and pneumonia cases have been prevented annually post vaccine introduction? UIP must be able to justify itself by quantifying disease prevention, calculating economic returns on investment [12]. Despite the fact immunization-protected children show higher cognitive development and better physical growth, helping to increase earning capacity and wealth creation [36], polio elimination in India was not widely recognized as a wealth-creating enterprise in India [37]. Why such major investments are not diverted to measures like improving sanitation, hygienic standards *etc*. that may prove more effective in long run instead of expending every time on launching vaccine for almost every other disease? UIP does not have, but urgently requires, a well-armed research and development wing to ask and answer all these questions.

## Way Forward

As the targets set under the Millennium Development Goals (MDGs) reached their end in 2015, the new global health paradigms have emerged under SDGs which focus on universal health coverage and sustainable development. A well-functioning UIP to reach out to every child will contribute to universal health coverage and healthier future generation. To achieve this, UIP will need strong underpinning of good governance and accountability at all levels. This will necessarily lead to improved program efficiency and more children will get immunized.

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## Compliance with Ethical Standards

**Conflict of Interest** None.

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