

Delivering the immunisation promise in India – a snapshot

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The Universal Immunization Programme (UIP) in India is one of the largest public health programmes worldwide in terms of logistics, geography and beneficiaries reached, as well as immunisation sessions conducted. The success of the UIP is crucial for a global reduction in the number of unimmunised children. It is believed that a strong immunisation programme provides a solid foundation for the expansion of maternal and child health and other public health interventions. In the last few years, UIP has seen an overall qualitative and quantitative improvement as a result of various interventions implemented by the government of India (GoI) and states under the umbrella of the National Rural Health Mission (NRHM). Some of these initiatives include flexible financing options to meet state needs, regular sessions microplanning, improved monitoring and supervision, use of auto-disable syringes, vaccine delivery to immunisation sites, hiring of additional trained vaccinators, funding provisions to cover underserved areas in urban slums, and strengthened cold chain systems to ensure vaccine availability and storage. This has resulted in improved access and increased use of services. Although some states have improved immunisation coverage, the performance in UIP is not uniform throughout the country, with wide variance in inter- and intrastate coverage and programme performance.

Situation analysis

Since the 1990s, the reported immunisation coverage has remained high, but evaluated coverage in some states has been markedly lower. A trend analysis of regular evaluations have shown a steady increase in the national level coverages of fully immunised children – from 43.5% (National Family Health Survey

[NFHS] 3, 2005–06)¹ to 54.1% (District Level Household and Facility Survey [DLHS] 3, 2007–08)² to 61% (UNICEF, Coverage Evaluation Survey [CES] 2009)³ – though these figures mask considerable inter- and intrastate variations. Some of the emerging concerns are stagnating immunisation rates, high dropout rates and a declining trend in some districts in key states, along with considerable geographical and social inequities. As per the UNICEF CES 2009, the percentage of children who are fully vaccinated ranges from 24% in Arunachal Pradesh to 87.9% in Goa. Four states have less than 50% of infants fully immunised, 14 states have 50–70% of children fully immunised and 13 states have more than 70% of children fully immunised.³

Since the 1990s, the reported immunisation coverage has remained high

The GoI, along with the states and other development partners, instituted mechanisms of regular review of programme performance. A national UIP review was undertaken in 2004.⁴ Review meetings and joint review missions are also organised. These reviews have noted strengths and constraints in UIP performance in India. These can be summarised under a few thematic areas:

- Technical and programme management
- Service delivery
- Data quality
- Vaccine logistics management
- Injection safety and unsafe waste disposal
- Social mobilisation for demand generation.⁵

Policy and strategy

The country has evolved mechanisms for continuous and sustained availability of technical inputs on programme implementation, regulatory aspects, new vaccine introduction and research.

The National Technical Advisory Group on Immunization (NTAGI) was established in August 2001 to help the UIP make informed decisions by providing advice on technical and operational issues inclusive of choice and scheduling of existing and planned vaccines. This group meets at least twice a year and whenever any urgent advice is needed.⁶

The country also develops multi-year plans to guide programme managers. These include operational strategies and costing to improve access and provide efficient and sustainable immunisation services countrywide.

The GoI is committed to the global polio eradication programme and a high-level group of national and international experts, the India Expert Advisory Group (IEAG) for polio, has been established. The IEAG meets periodically, and as and when required, based on the status of polio eradication, to take routine or urgent decisions with regards to acceleration of supplementary immunisation activities, modifications in surveillance policies, or changing approaches to programme communications and social mobilisation.⁷

In April 2011, on the NTAGI's recommendation, the National Vaccine Policy, with specific relevance to local vaccine needs, was formulated to guide decision-making and develop a long-term plan to strengthen the vaccine programme. This document provides a policy guideline and framework for the creation of an evidence base to justify the need for research and development (R&D), production, procurement, and quality assessment of vaccines for UIP. It also addresses strengthening processes, the evidence base, and the institutional and decision-making framework required for new vaccine introduction, vaccine security and programme management, and regulatory issues.⁸

Quality and standards

The Central Drugs and Standards Control Organization is the National Regulatory Authority in India. It approves all vaccines introduced in the country, grants

permission for clinical trials, registers and controls quality of imported vaccines, and lays down standards for updating the India Pharmacopoeia. It also approves licences as the Central License Approving Authority for vaccine manufacture, and coordinates and advises on activities to ensure uniform administration of all acts and rules in all matters. The Central Drugs Laboratory (CDL) performs lot release for all locally produced and imported vaccines.⁹

Financing

The UIP is 100% funded by central government. The Gol makes provisions for all expenses pertaining to vaccines and consumables, cold chain equipment, training, social mobilisation and the salaries of human resource staff.

Funding for disease control and eradication initiatives such as polio, measles and Japanese encephalitis (JE) is also provided for by the Gol.

Procurement and supply

The Gol procures all vaccines and consumables mandated under the UIP. Vaccines are procured through a national competitive bidding process and distributed directly by the manufacturers in strict cold chain conditions. India procures more than 500 million doses of mixed antigens every year for the UIP.

The introduction of new and underutilised vaccines, such as hepatitis B in the past and now the pentavalent vaccine DPT-HepB-*Haemophilus influenzae* b (Hib) by Gol has been supported by the GAVI Alliance.

Since the inception of the UIP, the Gol has established and maintained a wide network of more than 27,000 cold chain stores, consisting of government medical supply depots; state, regional/divisional vaccine stores; and district and primary health centre (PHC)/community health centre (CHC) vaccine storage points. This network has been the backbone of the UIP, ensuring that the right quantity and quality of vaccine reaches beneficiaries.^{10,11}

Service delivery

The UIP targets around 27 million surviving infants and 30 million pregnant women annually.

The administrative levels in India are national, state, district, and community development block. Within each block, there is usually a CHC, which caters to an average 175,000 of the population. The PHCs serve an average of 35,000 of the population. Each PHC has several subcentres, where an auxiliary nurse midwife (ANM) serves an average population of 5,600. In certain areas, these facilities are serving many more people than they were designed to, as the infrastructure has not always kept up with population growth.⁴ To assist the ANM in each village a new band of community-based functionaries called accredited social health activists (ASHAs) have been recruited. They act as a change agent for health and mobilise access to primary healthcare services rendered by the ANM.¹²

Nearly seven million immunisation sessions are held per year in India

Microplans are developed at each health facility level to estimate the number of beneficiaries and the logistics required. Workplans include type and name of service provider and the person assisting them (that is, the ASHA); numbers; date, time and place of immunisation sessions required as per beneficiary populations; area map; supervision; social mobilisation and training plans; and the budgets required. These sessions are conducted at fixed sites, hard-to-reach areas and outreach sites – the latter two are usually without any vaccine storage facilities.¹³

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Accelerated disease control and eradication

The country has targeted maternal and neonatal tetanus for elimination, measles and JE for control, and poliomyelitis for eradication.

Maternal and neonatal tetanus control activities started, along with the expanded programme on immunisation, in 1985 by providing two doses of tetanus toxoid (TT2) to all pregnant women (one dose if less than three years have passed since the previous pregnancy). In the 1990s,

supplementary immunisation campaigns were also conducted in some states with low TT2 coverage. Primary healthcare infrastructure was also expanded, and ANMs and other trained birth attendants deployed to perform clean deliveries. These facilities are being further strengthened under the NRHM and additional skilled birth attendants are being trained and put in place. A conditional cash transfer scheme, the 'Mothers' protection scheme', also encourages institutional deliveries. The Gol and its partners have been validating elimination of neonatal tetanus in the country since 2003 and, to date, 15 states and union territories have been validated.¹⁴

To help achieve measles elimination, a measles mortality reduction strategic plan was formulated in 2005. As a follow-up, the same 21 states with measles-containing vaccine first dose (MCV1) coverage of $\geq 80\%$, have introduced a second dose of measles-containing vaccine (MCV2) in routine immunisation. Fourteen states (361 districts) with MCV1 coverage of $< 80\%$ have introduced MCV2 mass vaccination campaigns using single antigen vaccine, targeting children aged nine months to ten years with subsequent introduction in routine immunisation. The campaigns plan to target 135 million children in 2010–12. Forty-five districts in nine states were immunised in 2010–11, 152 districts were immunised in 2011–12 and 164 districts will be targeted in 2012.^{15–17}

Efforts to eradicate polio started with the introduction of oral polio vaccine (OPV) in the UIP in 1985 and the first campaigns were held in 1986 in one state. These were expanded and Pulse Polio Immunization Days (National Immunization Days) were introduced in 1995. In 1997, the National Polio Surveillance Project (NPSP) was started by the Gol in collaboration with the World Health Organization (WHO) to provide technical and logistical assistance, and work closely with state governments and partner agencies to achieve polio eradication. The NPSP assists national and state governments with surveillance for acute flaccid paralysis (AFP) and poliovirus. It also assists with planning and monitoring of polio immunisation activities. This system is supported by a network of eight WHO-accredited laboratories. This system has assisted the Gol in planning and implementing targeted interventions based on the AFP surveillance data.¹⁸

The combined effect of these interventions; that is, routine immunisation

with trivalent and bivalent OPV, high-quality national and subnational immunisation days, mop-up rounds and a highly sensitive AFP surveillance system, has helped India become free of wild polio viruses for the last 12 months (Jan 2011–Jan 2012). Environmental sampling carried out in multiple locations has in the last 12 months been unable to detect any wild polio viruses.¹⁹

Nearly 27 years after launching its UIP, India has interrupted the circulation of indigenous wild polioviruses, thereby protecting millions of children.

In March 2012, the WHO removed India from the list of polio endemic countries.¹⁹

JE transmission has been widespread in India. The first evidence of its presence was in 1952 and the first clinical diagnosis was made in 1955. There have been various outbreaks, with the first major epidemic reported in eastern India in 1973. The National Vector Borne Diseases Control Programme (NVBDCP) has been conducting JE surveillance since 1978. A syndromic approach to report all cases of acute encephalitis syndrome was initiated in 2005 to capture as many cases as possible and identify endemic geographies. The Gol used mouse brain-derived inactivated vaccine until 2005. After a major outbreak in 2005, live attenuated SA-14-14-2 vaccine as a single dose has been used in the endemic districts, initially covering all those aged one to 15 years in campaigns and then immunising newer cohorts in UIP. Vector control and other interventions are being undertaken in the endemic districts.²⁰

Research and development

R&D and manufacturing of vaccines for locally prevalent diseases in India has always been a national priority and is also seen as an economic opportunity due to the presence of a strong and growing private vaccine manufacturing sector and a rapidly rising global demand for safe and affordable vaccines. Vaccines for major childhood killers such as pneumonia and diarrhoea, and for diseases with potential for outbreaks like JE, dengue, cholera and so on, are being developed. Vaccine R&D is undertaken both by academia and the vaccine industry. India also has a number of government-supported institutions, where vaccine-related research is conducted, such as the Indian Council of Medical Research (ICMR), Department of

Biotechnology (DBT), and other supported autonomous institutions. Links between these institutions, academia, industry and international institutions such as National Institutes of Health/National Institute of Allergy and Infectious Diseases, the Gates Foundation and others have been established and are yielding results.⁸

Immunisation safety

As the cohort being immunised is large and adverse events (AEs) can have a negative impact, the Gol lays an emphasis on ensuring immunisation safety – through reporting and monitoring of the cold chain, surveillance and management of an AE following immunisation – injection safety and waste disposal.

Surveillance, assessment and monitoring

India has a strong surveillance system for polio and is in the process of establishing a similar system for other vaccine-preventable diseases (VPDs). The country also has a disease surveillance project providing information on some VPDs. This system is also not able to provide accurate, timely information for making decisions.

The Gol undertakes periodic programme assessment along with its partners: UNICEF, WHO and USAID. It also conducts coverage surveys as a part of the NFHS and DLHS. UNICEF helps conduct coverage evaluation surveys and cold chain assessments. The

WHO reviews immunisation programmes to assist with strategic decisions.^{1–3}

Programme monitoring is carried out by all managers and partner organisations on a day-to-day basis. Monitoring reports are shared with managers to ensure that any observations are implemented.

New vaccines

Until 2002, the UIP offered Bacillus Calmette–Guérin, DPT/DT, OPV, measles and TT vaccines. Hepatitis B vaccine was added in 2002 and universalised in 2011. The JE vaccine was introduced in 2006 in endemic districts, through campaigns and routine immunisation programmes. The Gol introduced a pentavalent vaccine containing *Haemophilus influenzae* b (Hib) in two states in December 2011.

Some of the vaccines which may enter the national programme include rotavirus, injectable polio, typhoid, pneumococcal, dengue and cholera vaccines. Introduction will be based on guidance from the national vaccine policy and the NTAGI ■

Declaration of interest
None declared.

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Key points

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